



A Comparison of Hemostatic Patches Versus Pericardium Allograft for the Treatment of Complex Peyronie's Disease With Penile Prosthesis and Plaque Incision

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OBJECTIVE	To compare outcomes between hemostatic patches (HP) versus pericardium allografts (PA) for complex Peyronie's disease with erectile dysfunction managed with inflatable penile prosthesis (IPP) and plaque incision and grafting (PIG).
METHODS	We reviewed all men who underwent IPP with PIG for PD at our institution (4/2010-9/2018). PIG was performed via relaxing tunical incisions during IPP implantation following manual modeling if there was persistent curve $>30^\circ$ and/or significant narrowing. Tunic defects >2 cm were grafted. PA (Coloplast, Minneapolis, MN) or HP consisting of either Evarrest, Nu-Knit (Ethicon Inc., Somerville, NJ), or TachoSil (Baxter Int., Deerfield, IL) were used.
RESULTS	HP was placed in 18 men ($n = 10$ Evarrest, $n = 6$ Nu-Knit, and $n = 2$ TachoSil), 15 had PA. There was no difference in mean age, preoperative curvature (HP: 75° vs PA: 78°), or grafted area (HP: 11.9 cm^2 vs PA: 10.9 cm^2) between HP and PA cohorts. Mean operative time was shorter for HP (122 vs 166 minutes, $P = .01$). Median follow-up: 6.6 months (range: 2-27 months) for HP and 34.6 months (range: 13-103 months) for PA. Residual curvature $>20^\circ$ was present following HP in 16.7% ($n = 3$) and PA in 13.3% ($n = 2$; $P = 1.0$). There were no complications attributable to HP/PA material and no IPP herniation through the tunical defect. Postoperatively, 94.4% ($n = 17$) of HP and 93.3% ($n = 14$) of PA patients were engaged in penetrative intercourse ($P = 1.0$).
CONCLUSION	HP are effective materials to cover the tunical defect over an IPP following plaque incision for PD. HP outcomes are similar to PA, while operative time is shorter for HP. UROLOGY 129: 113–118, 2019. © 2019 Elsevier Inc.

Peyronie's disease (PD), a disorder characterized by fibrosis of the tunica albuginea of the penis, presents with a heterogeneous complex of symptoms that includes penile deformity, sexual dysfunction, and psychological bother.¹ Up to 9% of men are affected by PD during their lifetime.² Treatment options including oral and topical therapy, intralesional injections, and penile traction therapy have been studied with varying levels of clinical evidence, and efficacy is highly variable as well.³ However, in patients with bothersome penile curvature, surgical straightening with penile plication or incision/excision

with grafting is the most reliable means for providing patients with a functionally straight phallus.⁴

Erectile dysfunction (ED) is commonly reported by men with PD, and studies have suggested that up to 45% of patients report difficulty achieving or maintaining a strong erection at the time of initial evaluation.⁵⁻⁷ Psychological bother and penile pain, as well as age and other comorbid conditions have been found to increase the risk of experiencing ED and PD concurrently.⁸ Historically, veno-occlusive dysfunction from tunica albuginea fibrosis was thought to underlie the increased risk for ED. More recent work from Chung et al in 2011 found that arterial insufficiency is highly prevalent in these patients as well.⁷ Penile ultrasonography with intracavernosal injection of an erectogenic agent at the time of initial curvature assessment provides objective evidence of these processes and is commonly utilized to assist with decision-making regarding treatment.⁷ In the absence of treatment, 40%-60% of

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patients with PD report a decline in sexual function.^{1,9} ED is also a potential side effect with penile straightening procedures including plaque excision/incision and grafting or tunical plication.¹⁰

In those patients who desire definitive management with surgical penile straightening, but who would otherwise be at high risk for inadequate penile rigidity following surgical reconstruction secondary to baseline ED (as determined by history, physical examination, and preoperative testing with intracavernosal injection and penile ultrasonography), inflatable penile prosthesis (IPP) placement should be considered the treatment of choice.^{10,11} Less severe preoperative penile curvature can often be corrected with IPP placement alone. For instance, Mulhall et al found that no patients with preoperative penile curvature $<30^\circ$ required additional straightening maneuvers.¹² In those patients with more moderate curvature, manual modeling, first described by Wilson and Delk in 1994, will result in a functionally straight phallus in the majority of patients.^{13,14} More invasive options such as tunica plication and plaque incision with or without grafting are reserved for patients whose curvature or other penile deformity, such as hourglass or indentation, is more severe and in those where modeling does not result in a functionally straight penis ($<20^\circ$).¹⁵

Various graft materials have been utilized at the time of plaque incision and grafting (PIG) with concurrent IPP implantation, and no strong evidence exists to support one graft type over another.¹⁵ Over the last several years, a collagen fleece hemostatic agent known as TachoSil (Baxter Healthcare Corp, Deerfield, IL) has been popularized for tunical grafting with and without IPP placement in patients with PD and severe penile curvature.¹⁶⁻¹⁸ Proposed benefits include its intrinsic hemostatic properties and ability to avoid suture placement, which can increase operative time and put the underlying prosthesis device at risk for needle injury.

Surgeon preference and institutional availability remain the most important drivers of graft utilization. In fact, at our institution and others, procuring TachoSil has been difficult, prompting us to utilize alternative types of sutureless hemostatic patches (HP) including Nu-Knit and Evarrest (Ethicon Inc., Somerville, NJ). Yet, there is relatively little information available regarding these alternatives. Herein we sought to evaluate our experience with HP to cover the tunical defects following plaque incision at the time of IPP placement for concurrent PD and ED. We further compared outcomes between HP and pericardium allograft (PA).

MATERIAL AND METHODS

We conducted a retrospective cohort study of all men with complex PD that underwent IPP and PIG with HP versus PA at our tertiary care medical center from 4/2010-9/2018. Complex PD was defined as curvature $>60^\circ$ and the presence of hinge effect and/or narrowing. All patients had preoperative phosphodiesterase type 5 inhibitor drug refractory ED and underwent IPP implantation.

Data was collected on baseline patient characteristics including comorbid diabetes, hypertension, hyperlipidemia, and smoking status. Preoperative evaluation involved creation of an artificial erection at the time of penile duplex ultrasound as well as objective assessment of penile curvature and presence of narrowing, plaque calcification, and hinge effect. Intraoperative data included graft size and operative duration. Postoperative outcomes were compared between the HP and PA cohorts and included evaluation of residual curvature, complications, need for revision surgery, and ability to engage in penetrative intercourse. A single surgeon (LAL) performed all procedures.

Evaluation of penile deformity was conducted pre and postoperatively during creation of an artificial erection with an intracavernosal injection (most commonly Trimix: papaverine 30 mg/mL, phentolamine 1 mg/mL, alprostadil 10 mcg/mL at a starting dose of 0.1 mL). Degree of curvature was measured with a goniometer and narrowing was assessed by measuring penile circumference at the proximal and distal shaft as well as at the site of the defect. Hinge effect was determined by the presence of acute angulation with instability at the site of the defect with gentle downward axial pressure on the glans.

PIG was performed when there was shaft instability due to indentation deformity after IPP placement or when residual curvature was $>30^\circ$ after IPP placement with manual modeling in the absence of shaft instability. In all cases, an IPP (AMS CX700, Boston Scientific, Marlborough, MA; Titan, Coloplast, Minneapolis, MN) was implanted via a penoscrotal or subcoronal approach.¹⁹ The penile shaft was degloved via a circumcising subcoronal incision. When the IPP was placed via a penoscrotal approach, a second subcoronal incision was required. Buck's fascia was then elevated over the point of maximum curvature. With the IPP maximally inflated, a transverse incision with cautery (30 watts) was made to expand the tunical defect until adequate straightening and/or girth restoration was achieved. The corners of the incision were darted to prevent cicatrix contracture. Patients with compound penile curvature requiring more than 1 plaque incision were excluded from analysis. Tunical defects >2 cm were covered with either PA (Tutoplast, Coloplast, Minneapolis, MN) or HP consisting of either Evarrest, Nu-Knit (Ethicon Inc., Somerville, NJ), or TachoSil (Baxter Int., Deerfield, IL; Fig. 1). All HP were sized 0.5 cm larger than the tunical defect on all sides. PA was sized 10% larger than the defect. The corners of the PA are secured to the tunica albuginea and the IPP is deflated. This reduces the likelihood of inadvertent injury to the cylinders while the graft is sutured to the tunica albuginea circumferentially with running 4-0 PDS. HP did not require suturing.

Buck's fascia was reapproximated to cover over all HP and PA to provide further structural and vascular support. A light compression wrap was placed and patients were discharged on 14 days of oral antibiotics. The IPP was left inflated at 60%-70% for 14 days and subsequently deflated for 4 weeks. Patients were encouraged to cycle the device daily thereafter and sexual activity was allowed to resume no sooner than 6 weeks postoperatively.

Data analysis was conducted with PASW Statistics 18 software (SPSS, Chicago, IL). Categorical data were reported as counts and percentages. A Pearson Chi-square univariate analysis was used to compare binomial variables. Continuous variables were reported as mean and standard deviation with statistical analysis utilizing a 2-sample *t* test. Continuous variables that did not follow a normal distribution were reported as median and range with statistical analysis conducted via a

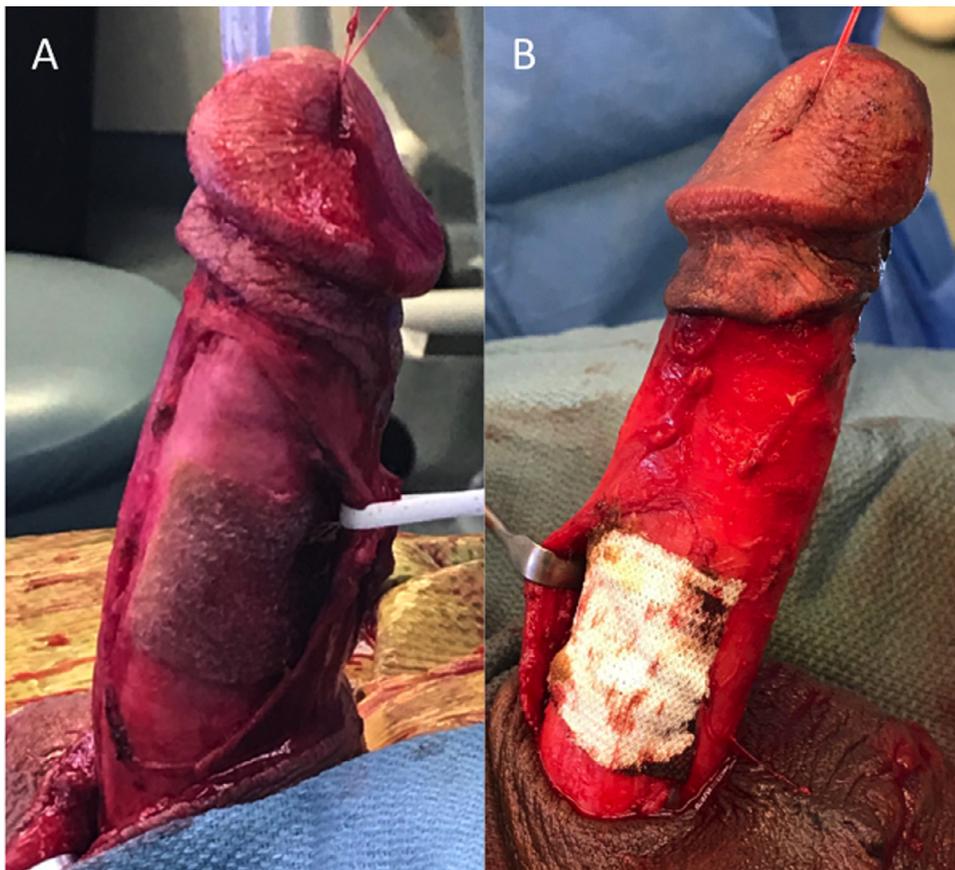


Figure 1. Intraoperative images of (A) Evarrest and (B) Nu-Knit HPGs placed over the defect in the tunica albuginea following placement of inflatable penile prosthesis. (Color version available online.)

Mann-Whitney *U* test. Statistical significance was determined using a *P* value < .05 for all analyses.

RESULTS

We identified a total of 33 patients who underwent IPP with PIG. HP was utilized in 18 patients including TachoSil (*n* = 2, 11%), Nu-Knit (*n* = 6, 33%), and Evarrest (*n* = 10, 56%). Preoperative patient demographics including age, diabetes, hyperlipidemia, hypertension, smoking status, penile curvature, and the presence of calcification, narrowing/indentation or hinge-effect did not significantly differ between those who underwent HP or PA (Table 1).

Intraoperative data are shown in Table 2. The majority of IPP devices placed were Coloplast Titan (29/33, 88%), and most devices were implanted through a penoscrotal approach with a subsequent subcoronal degloving incision as indicated for PIG (26/33, 79%). Notably, mean operative time including anesthesia time was significantly shorter for patients who underwent HP as compared to PA (122 minutes vs 166 minutes; *P* = .001). There was no significant difference in mean operative time among different HP materials.

Median follow-up was significantly shorter in those patients who underwent HP compared with PA as we only recently introduced HP to our operative approach [6.6 months (range 2-27) vs 35 months (range 13-103); *P* < .001]. At the time of last follow-up, clinically significant residual penile curvature >20° was identified in 2/15 patients (13%) with PA and 3/18

patients (17%) with HP (*P* = 1.0). Of these patients, bothersome residual curvature was noted in 2/15 patients (13%) with PA and 1/18 patients (6%) with HP (*P* = .58). Data regarding the 5 patients with clinically significant residual curvature after HP is available in Table 3. In total 17/18 patients (94%) with HP and 14/15 (93%) with PA reported satisfactory penetrative intercourse postoperatively (*P* = 1.0). At the time of last follow-up, a total of 4 patients (12%) underwent revision surgery including IPP explant for distal cylinder erosion (HP, *n* = 1), cylinder revision for proximal migration (PA, *n* = 1), device explant for dissatisfaction (PA, *n* = 1), and repeat PIG procedure with PA for recurrent 60° ventral penile curvature (PA, *n* = 1). No complications were identified that could be directly attributed to the graft material, and to date no patients in this cohort have experienced device herniation through the tunical defect, bothersome sensory deficits, IPP malfunction including fluid leak, or IPP infection.

Regarding graft cost at our institution, Nu-Knit is the least expensive at \$42 USD. Evarrest, TachoSil, and PA (Tutoplast) are similar at \$775, \$650, and \$693 USD, respectively.

COMMENT

In this study, we introduce Nu-Knit and Evarrest as viable HP materials in addition to TachoSil, and compare outcomes to PA. We found similarly high rates of penile straightening and device survival with both HP and PA, while operative times were significantly shorter with HP.

Table 1. Patient demographics

	HP* (n = 18)	PA† (n = 15)	P Value
Age (years), mean (SD)	59.6 (8.8)	57.6 (6.3)	.48
Diabetes, n (%)	5 (28)	4 (27)	.94
Hyperlipidemia, n (%)	7 (38.9)	4 (26.7)	.71
Hypertension, n (%)	9 (50)	10 (66.7)	.48
Smoker, n (%)	10 (56)	4 (27)	.10
Preoperative curvature (degrees), mean (SD)	74.7 (24.5)	77.7 (31.2)	.77
Calcification, n (%)	10 (56)	9 (60)	.68
Narrowing/indentation, n (%)	12 (67)	11 (73)	.68
Hinge effect, n (%)	5 (28)	5 (33)	.51

* Hemostatic patch.

† Pericardial allograft.

Thus, HP materials such as Nu-Knit, Evarrest, and TachoSil should be strongly considered for concurrent patching procedures at the time of IPP placement for complex PD.

Multiple different graft materials have been utilized in the setting of plaque incision for complex PD including synthetic material, vein, dura mater, tunica vaginalis, porcine small intestine submucosa (SIS), and cadaveric human, or bovine pericardium. Most commonly, PA and porcine SIS grafts are utilized (Surgisis ES, Cook Urological, Spencer, IN).²⁰⁻²² Of these traditional grafts that must be sutured into place, we prefer PA because it has similar properties to the tunica albuginea in that it is strong, thin, holds suture well, and has minimal graft contraction. The tissue is processed into an acellular matrix, which promotes native tissue ingrowth while eliciting minimal inflammatory response.²³ SIS is also processed into an acellular matrix with similar properties to PA, however, in the absence of an IPP, it is prone to graft

contraction and is associated with recurrent curvature in 37%-57% of cases.²⁴⁻²⁶ While both SIS and PA do not involve donor site morbidity, they do require meticulous suturing into the tunica albuginea defect, which can place the IPP at risk of needle puncture and will increase operative times.

HP offer an alternative to traditional grafts without the requirement of being sutured into place. It is important to note that HP are best utilized when adequate Buck's fascia is available to cover and maintain the graft in place in order to provide the desired hemostasis and structural support. Additionally, for larger defects >4 cm along the longitudinal border, we prefer PA to insure hemostasis and structural support for a longer duration.

We evaluated our experience with the HP Nu-Knit, Evarrest, and TachoSil to cover the defect in the tunica albuginea at the time IPP placement with plaque incision. Nu-Knit is comprised of a cellulose mesh, while Evarrest has a similar cellulose mesh with the addition of thrombin and fibrinogen on 1 side of the patch, thus providing additional hemostatic properties. The absorption time is more rapid for Nu-Knit at 7-14 days relative to approximately 8 weeks for Evarrest.^{27,28} Conversely, TachoSil is an equine collagen fleece that is depleted of immunogenic epitopes and has human fibrinogen and thrombin on 1 surface. TachoSil adheres to the native tunica albuginea, which is in contrast to Nu-Knit and Evarrest, which are strictly hemostatic. In swine studies of TachoSil applied to liver wounds, histologic remnants of the patch were observed in all subjects at 26 weeks and 75% at 52 weeks as granulation tissue forms a capsule around the patch.²⁹

Grafting with TachoSil has been previously described in the literature with and without IPP placement.¹⁷ A recent comparative study of patients undergoing IPP implantation and concurrent PIG with TachoSil versus

Table 2. Intraoperative data for inflatable penile prosthesis with concurrent plaque incision and grafting

		HP* (n = 18)	PA† (n = 15)	P Value
IPP type, n (%)	Coloplast Titan	14 (78)	15 (100)	.08
	Boston Scientific CX 700	4 (22)	0 (0)	
IPP approach, n (%)	Penoscrotal	12 (67)	14 (93)	.07
	Subcoronal	6 (33)	1 (7)	
Patch/Graft defect area (cm ²), mean (SD)		11.9 (6.0)	10.9 (6.7)	.64
Operative length (min), mean (SD)		122 (22.8)	166 (41.4)	.001

Bold denotes a *p*-value of <0.05 indicating statistical significance.

* Hemostatic patch.

† Pericardial allograft.

Table 3. Residual curvature after grafting

Patient	Patch/Graft Type	Preoperative Curvature	Residual Curvature	Patient Bothered by Residual Curvature?
A	Evarrest	115° dorsolateral	20°	No
B	Nu-Knit	95° dorsolateral	25°	No
C	Evarrest	85° ventral	35°	Yes
D	Pericardium allograft	90° lateral	25°*	Yes
E	Pericardium allograft	50° lateral	60°†	Yes

* Patient ultimately underwent device explant for dissatisfaction with device.

† New onset ventral curve postoperatively.

SIS found that operative times for the TachoSil cohort were significantly shorter by a mean of 25 minutes, while there were no differences in major intra or postoperative complications.¹⁸ We found a significant decrease in operative times associated with HP over PA, regardless of HP material used, by a mean of 44 minutes.

In our study, functional outcomes were similar between the HP and PA cohorts. Postoperatively, 94% of the HP cohort was able to engage in penetrative intercourse, which was similar to patients undergoing PA placement. Additionally, there was no difference in clinically significant residual curvature ($>20^\circ$) or patient-reported bothersome residual curvature. There were also no instances of IPP herniation or complications attributable to the graft material in our HP cohort. Further, HP are rarely ever palpable and there have been no patient-reported instances of a palpable, bothersome patch.

As we have gained experience with HP, our selection of specific HP material has evolved. TachoSil has become prohibitively difficult to obtain at our institution and we have discontinued its use as a result. We have found that Evarrest, in comparison to Nu-Knit, has a thickness most similar to the tunica albuginea and is a more easily manipulated material. Further, Evarrest provides notably longer coverage of the defect until absorption relative to NuKnit. As a result, we now largely utilize Evarrest for this procedure.

The cost of Evarrest and PA at our institution is similar. Therefore, the cost-effectiveness of utilizing HP over PA lies in the significantly decreased operative time of nearly 45 minutes. This decreased operating room time is because HP do not need to be sutured into place, as all other steps in the procedure are the same for PIG over an IPP for HP and PA.

While our study is the first to describe Nu-Knit and Evarrest as HP material at the time of IPP placement and PIG, there are several limitations including the retrospective, nonrandomized design and the small sample size. Follow-up for PA was significantly longer than for HP, as HP represent a more recently utilized patch material compared with PA, which has been in use for a longer period of time. The majority of patients experience stabilization of postoperative curve correction after IPP placement by 3 months.³⁰ Therefore, our follow-up of over 6 months for the HP cohort did allow for evaluation of stable residual curvature.

Additionally, a greater proportion of patients underwent IPP placement via a penoscrotal approach. However, in our more contemporary experience, we utilize a subcoronal approach when feasible to allow for a single incision for both IPP placement and PIG. We specifically choose a subcoronal approach for patients with severe deformity including curvature $>90^\circ$ or extensive grade 3 calcification, as we anticipate that manual modeling will not adequately correct the deformity. Finally, given the retrospective nature of this study, we did not have validated questionnaires to evaluate postoperative sexual function and patient satisfaction. Instead, we noted

restored function as the ability to engage in penetrative sexual intercourse.

CONCLUSION

HP offer a viable graft material at the time of IPP implantation with PIG for complex PD with similarly excellent functional outcomes, improved cost-effectiveness, and minimal complications when compared to PA, while requiring significantly less operative time.

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