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The use of Tutoplast® pericardial grafting in male reconstructive surgery: A literature review and case series

***Corresponding Author:** Jordan Sarver*

Email: j.sarver1011@gmail.com

Jordan Sarver*; Ali Baydoun; Lauren Nesi; Mazen Abdelhady

Department of Urology, Detroit Medical Center, USA.

Abstract

Urologist are faced with a variety of diseases that impact the male genitals and lead to tissue loss. Flaps and grafts are used in some scenarios to cover different tissue deficits. Reconstruction and treatment of genital pathology aim to preserve genital function, quality of life and to restore cosemesis. Among graft options, there exists Tutoplast® pericardium graft, which comes in one formulation as a pericardium allograft made of a thin, decellularized collagen matrix. Tutoplast® pericardial graft may be used as an alternative for grafting the tunica albuginea after Peyronie's plaque excision. Additionally, this grafting technique has been seen with corporal defect repairs during inflatable penile prosthesis surgery. Lastly, Tutoplast® grafting can be used during complex reconstructive cases after tissue debridement for Necrotizing Fasciitis. Here we present uses of Tutoplast® pericardial grafting at our institution for reconstruction of patients with a variety of tissue pathology including inflammatory, infectious, and fibrotic disease. We will review the indications for use and the steps involved for proper placement during different surgical procedures.

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Introduction

Urologist may be faced with patients who suffer from genital skin loss. Etiologies include infection, trauma, burns, malignancy, and other diseases [1]. There continues to be advances in applications of skin grafts within urology. Reconstruction and treatment of genital pathology aim to preserve genital function, quality of life and to restore cosemesis [1]. Options for reconstruction of the genital tissue includes the use of flaps versus grafts. There are a variety of grafting techniques used in urological reconstruction [2]. Synthetic materials have been used in prior urological reconstruction, however with noted complications of infection and fibrosis [3].

Among graft options, there exists Tutoplast® which can be made from cornea, sclera, fascia lata, or pericardium and treats a variety of different disorders, including ocular disease [4]. Tutoplast® pericardium is one graft option that is dehydrated pericardium processed from donated human tissue and made of a thin, decellularized collagen matrix (Figure 1) [5]. The graft is preserved via a Tutoplast® sterilization process. For further discussion within urology and the use at our institution, we will be referring to the Tutoplast® pericardium as the grafting choice used and described. Tutoplast® pericardial grafting has been used as an alternative for tunica albuginea defects after Peyronie's plaque excisions [6]. Authors report resolution of penile curvature in all patients with good sexual function results [6]. Tutoplast® pericardium may also be used in the setting of penile implantation. A known risk factor of Inflatable Penile Prosthesis (IPP) placement is corporal perforation [7]. Prior case reports have used Tutoplast® pericardial grafting to repair corporal defects during a complex penile reimplantation [8]. Repair of the corpora may include different materials and requires careful selection to improve healing and patient outcomes [8]. Grafting material is ideally durable and flexible

to allow for erections and to accommodate the implant device within the corpora [8]. Overall Tutoplast® pericardium grafting is used in a variety of urological procedures. Here we review the indications for use and steps involved for placement of the graft. At our institution we have experience using the graft for surgeries including Peyroronie's disease, corporal repair during IPP placement, and for coverage of genital skin loss after infectious debridement.

Methods and case examples

The initial evaluation of a patient for the use of a graft consists of obtaining a thorough history and physical examination. Details of the patient's medical history is key, highlighting the presence of diabetes, immunosuppression, and chronic steroid use which may contribute the graft take and wound healing. History of any prior urological or abdominal surgeries should be elicited. We discuss anticoagulation status for those taking blood thinners. A detailed physical exam is important and includes assessment of the male genitourinary system. Pre-operative antibiotics are ordered for these surgeries based upon the AUA best practice guidelines as well as consideration for local antibiotic nomograms.

For those undergoing IPP placement or revision, we routinely obtain hemoglobin A1c values for patient's prior to IPP placement due to the risk of device infection. We exam the indwelling IPP for implant reconstruction to assess for any potential malfunction or erosion if a revision of the implant is planned. We routinely obtain a pre-operative urine culture for those undergoing surgical intervention of the genitourinary tract, including penile prosthesis surgeries. Specifically, for Peyronie's disease, we evaluate the size of the penile plaque in as well as the penile curvature degree estimation. Patients are encouraged to bring a photo of their erect penis to evaluate the degree of curvature. Lastly, we evaluate and describe the wound bed for those patients with prior wounds who are to undergo debridement with graft placement.

Patient preparation

The patient is ultimately evaluated in the operating room prior to placement of the graft. The patient usually remains in the supine position during the reconstructive portions of the procedure. Any hair bearing skin is shaved. Preparation of the skin is performed in a standard fashion using betadine or chlorhexidine. In the setting of urology, our institution uses the pericardial grafts. Measure the defect intended to be treated after plaque excision, or excisional debridement depending on the type of surgery being performed. Of note, the total length requirement for the Tutoplast® pericardial graft will be 10% more than the measured amount. Once the defect is measured, it will be time to open and use the graft.

The Tutoplast® pericardial graft will come packaged and sterilized per the manufacturer. Use and handling of the graft is detailed within the packaging instructions. This graft is a single use product and is to be used on only one patient. Per the packaging instructions, the graft is opened and passed onto the sterile field. The implant re-hydrated by soaking the graft in room temperature saline solution for 30 minutes. Cut the Tutoplast® to cover the desired defect, again measuring 10% more than the measured amount. Per the instructions, the graft may be secured using absorbable or non-absorbable suture by placing stitches 2-3 mm from the edge of the graft.

Device use/Procedural steps

Case 1

For the use in Peyroine's disease, a few specific considerations are worth noting. We begin by palpating for a plaque and once the plaque is located, we induce an artificial erection by injection normal saline into the corpora. We then proceed with excision of the Peyronie's plaque. We then measure the defect prior to placement of the Tutoplast® graft. After plaque excision or wound debridement, the Tutoplast® graft is secured with a running 2-0 or 3-0 PDS to secure the graft. We used PDS® to allow for more tensile strength compared to Prolene®, a non-absorbable suture.

Case 2

For the use in penile reconstruction, sharp debridement is especially important to excise all nonviable tissue while maximally preserving healthy structures. This allows for maximal debridement of infectious tissue with a healthy bed to improve graft take. One patient in our practice presented with a large necrotic penile wound after strangulation from a bottleneck. Penile debridement revealed a deep area of necrotic tissue along the proximal ventral penile shaft, penetrating beyond the tunica into the superficial corpora cavernosa. Sharp debridement was performed to excise all nonviable tissue while maximally preserving healthy structures using a combination of sharp debridement with Metzenbaum scissors as well as Bovie electrocautery in order to delineate healthy, bleeding tissue from necrotic tissue. A 6x6 cm Tutoplast® Pericardium Allograft was secured and overlaid on the ventral penile defect. The graft was secured to the tissue using a 3-0 PDS in a running fashion and anchored to the tunica albuginea and median raphe, with Surgifoam® (Ethicon, Inc., Cincinnati, OH) (Figure 1). Prior to discharge the patient's graft revealed good cosmesis and take (Figure 2). At seven months postoperatively, the patient was doing well, and the prior debridement bed was healing appropriately with stable graft take and good cosmetic results. This was a successful example of a penile sparing approach for a patient presenting with gangrene and requiring penile debridement [12].

Case 3

Additionally, at our institution we evaluated a patient who presented after a penile implant placement and underwent a mini salvage procedure a year later when one of the cylinders were replaced with a malleable and the other corpora was left without a cylinder for healing purposes. He eventually presented again to have a malleable penile implant placed bilaterally. We performed an insertion of a left malleable prosthesis with Tutoplast® graft. The left corpora was exposed in the usual fashion. A new malleable implant was placed, however there was a significantly narrowed left corporal body and there was difficulty in approximating the edges of the corporotomy without tension. The defect was measured and the decision was made to place a Tutoplast® graft to cover the tissue defect (Figure 3). A 2x5 cm Tutoplast® graft was used to close the corporotomy off tension with 2-0 PDS® sutures (Figures 4-6). The rest of the fascia and tissue was closed in a normal fashion. The patient was discharged home the next day and healed well postoperatively.

Figure 1: Tutoplast® pericardium allograft example [5].

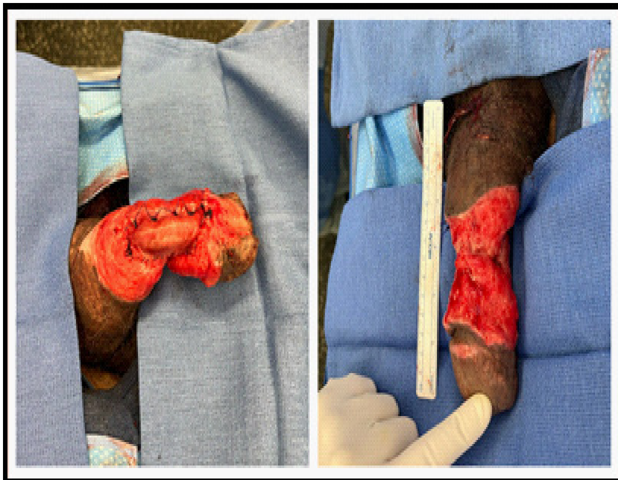

Figure 2: Immediate postoperative appearance following third and final debridement and reconstructive graft. Reconstruction grafting with Tutoplast® pericardium [12].

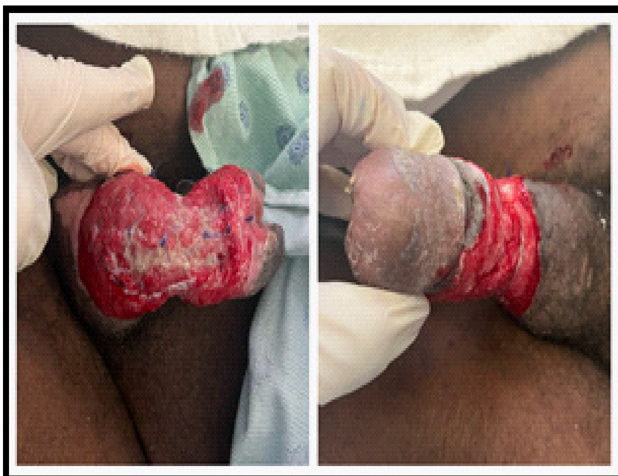

Figure 3: Postoperative follow-up prior to discharge. Well-perfused margins; no graft rejection [12].

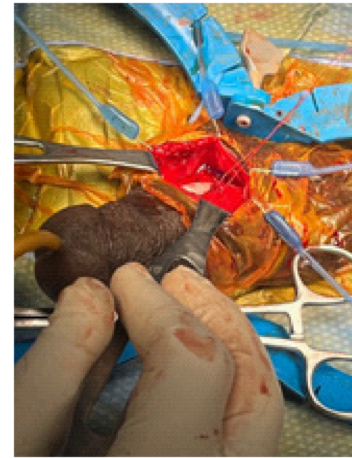

Figure 4: Intraoperative exposure of the corporal defect and placement of Tutoplast® pericardial graft for tissue coverage.

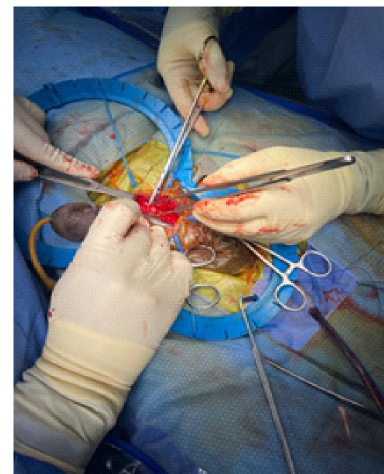

Figure 5: Intraoperative usage of a 2x5 cm Tutoplast® pericardial graft to close the corporotomy off tension with 2-0 PDS sutures.

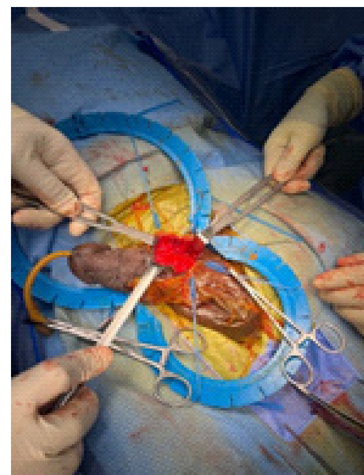

Figure 6: Final appearance of coporotomy closure after placement of Tutoplast® pericadial graft.

Post-op management

Post operative management will consist of ensuring proper graft take and health. For penile debridement, routine follow up in the office is important to ensure the skin is healing appropriately. Upon discharge, patient will usually come to clinic within 1-2 weeks after surgery and then approximately 1 month later. The wound is examined to ensure proper healing and perfusion of the graft. After Peyroine's plaque excision and grafting a post operative visit is scheduled in 1-2 weeks again noting the healing of the penile skin. After IPP placement or revision the patient is scheduled at 1 week to deflate the implant and ensure proper healing of the incision. A Foley catheter is left overnight and removed the next day after IPP placement or revision. The patient is then given the ability to use the implant for intercourse at the 6-week mark as long as they are healing appropriately. The patient can usually shower after discharge home from the hospital. They will avoid bathing or soaking in tubs, lakes, or pools for 2-4 weeks after surgery. They are usually advised to avoid heavy lifting during the immediate postoperative period. As needed pain medication including

acetaminophen and short duration opioid medications for pain breakthrough are used to assist with any postoperative discomfort and pain.

Discussion

In this study, we reviewed the indications for use and steps involved for placement of the graft. At our institution we have experience using the graft for surgeries including Peyroine's disease, corporal repair during IPP placement, and for coverage of genital skin loss after infectious debridement. Hellstrom et. al report their experience using Tutoplast® grafting for the tunica albuginea after Peyronie's plaque excision. There was a total of 11 patients with penile curvature interfering with sexual intercourse after 12 months of conservative therapy. The pericardium was used to graft the cavernosal defect after surgical excision of the plaque. In 3 of the patients, a penile prothesis was simultaneously placed due to erectile dysfunction. Penile curvature resolved in all of the patients with normal sexual function reported after 14 months. No postoperative rejection or infection was noted. This study demonstrates the effective use of cadaveric pericardium as a graft material for cavernosal defects after Peyronie's plaque excision with overall good patient satisfaction [6]. Tutoplast cadaveric pericardium outcomes after Peyronie's plaque excision were reported additionally by Leungwattanakij et al. Some of the men received penile implants at time of plaque excision. A mean follow-up of 30 months was used for each of the 11 men treated in this cohort. All patients reported resolution of curvature at 14 months post op. Of the men who did not receive implants, three with small plaques did well, and the remaining 5 with large plaques reported late erectile dysfunction. The authors conclude that for patients not undergoing prosthesis, a better long term outcome was seen for those with small to medium size (<2x5 cm) and dorsally located plaque [9].

In a case report published in 2023, authors reported a patient who underwent a IPP explant and replacement. During reimplantation, excessive scar tissue was noted distally and this required scar excision. The defect was covered using a Tutoplast® pericardium allograft and followed the patient outcomes. The graft (6 cm x 3 cm) was placed over the left distal tunica albuginea where the tissue was weak and thin over the implant cylinder. Authors report the patient has been healing well without any issues with good sexual function outcomes [8]. Several different grafting approaches in transgender patients have been utilized [10]. Prior studies report the use of human cadaver pericardium (Tutoplast®) in IPP neophallus placement for proximal and distal cylinder coverage for better cosmetics and tissue coverage. They followed the patients for postoperative satisfaction and device functionality. Both patients in this study reported satisfactory erectile and sexual function at a follow up of 14 and 23 months postoperatively, which highlights beneficial preliminary outcomes for this technique [10]. Tutoplast® has also been used in the setting of urethral defects. Mahdi, et. al report on a patient who had a history of an IPP placement and a new urethral mass. He underwent total urethrectomy for a urethral mass and a graft was used to reinforce the thinned ventral tunica albuginea after urethrectomy. At six month follow up, the authors report the patient had a good recovery and normal IPP functionality [11].

Conclusion

Urologist may be faced with patients who suffer from genital skin loss. Advances in applications of skin grafts within urology continue to be studied within the literature. One option for reconstruction of the genital tissue includes the use of Tutoplast® pericardium graft. Tutoplast® pericardium graft has been used in various urological procedures [13]. The process to create the graft involves sterilization and purification of human tissue in order to design a safe and durable graft [13]. Possible complications of graft placement can include graft loss, immune mediated reactions towards the graft, wound infections or healing issues [14]. At our institution, we have utilized Tutoplast® pericardial grafting for several urological conditions requiring grafting including Peyronie's disease, penile implants, and penile debridement cases. All patients were followed with satisfactory clinical and cosmetic outcomes postoperatively. More research is required with graft material to expand the use of these materials within urological surgery.

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