Complications of grafts used in female pelvic floor reconstruction: Mesh erosion and extrusion

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ABSTRACT

Introduction: Various grafts have been used in the treatment of urinary incontinence and pelvic prolapse. Autologous materials such as muscle and fascia were first utilized to provide additional anatomic support to the periurethral and pelvic tissues; however, attempts to minimize the invasiveness of the procedures have led to the use of synthetic materials. Complications such as infection and erosion or extrusion associated with these materials may be troublesome to manage. We review the literature and describe a brief overview of grafts used in pelvic floor reconstruction and focus on the management complications specifically related to synthetic materials.

Materials and Methods: We performed a comprehensive review of the literature on grafts used in pelvic floor surgery using MEDLINE and resources cited in those peer-reviewed manuscripts. The results are presented.

Results: Biologic materials provide adequate cure rates but have associated downsides including potential complications from harvesting, variable tissue quality and cost. The use of synthetic materials as an alternative graft in pelvic floor repairs has become a popular option. Of all synthetic materials, the type I macroporous polypropylene meshes have demonstrated superiority in terms of efficacy and fewer complication rates due to their structure and composition. Erosion and extrusion of mesh are common and troublesome complications that may be managed conservatively with observation with or without local hormone therapy, with transvaginal debridement or with surgical exploration and total mesh excision, dependent upon the location of the mesh and the mesh type utilized.

Conclusions: The ideal graft would provide structural integrity and durability with minimal adverse reaction by the host tissue. Biologic materials in general tend to have fewer associated complications, however, the risks of harvesting, variable integrity of allografts, availability and high cost has led to the development and use of synthetic grafts. Synthetic grafts have a tendency to cause higher rates of erosion and extrusion; however, these complications can be managed successfully.

Key words: Biomaterials, erosion, management, synthetic mesh

The use of graft materials in pelvic floor reconstruction is now a common practice. The evolution of grafts from autologous muscle and fascia has produced new materials that will hopefully prove to be efficacious and durable. This review aims to provide an overview of the different materials available for use in pelvic floor surgery and to discuss the potential complications, in particular erosion and extrusion, associated with synthetic materials.

Graft Material

The decision to use a graft in the repair of the pelvic floor is based on a number of factors including the tissue quality of the patient, history of previous repairs and concomitant procedures to be performed. The ideal material should be strong, sterile, permanent, nonallergenic, inert, free of risk of infection, infectious transmission, erosion and extrusion and affordable. In 1997, the female stress urinary incontinence clinical guidelines panel performed a meta-analysis of the literature from 1994-1997 and found an overall vaginal extrusion rate of 0.0001% vs. 0.007% for autologous and synthetic materials, respectively. Urethral erosion rates were noted in 0.003% and 0.02%, respectively.

BIOLOGIC MATERIALS

Graft materials may be categorized as biologic or synthetic. Biologic materials include autologous grafts, allografts and xenografts. Biografts were initially used for their histological similarity to human tissue, in vivo tissue remodeling and reduced erosion rates. Specific advantages and disadvantages are noted with each type of graft material.

Autologous grafts

Autologous grafts that are commonly harvested for repairs are rectus fascia and fascia lata. Clear advantages to using the patient's
own tissue are decreased risk of erosion, rejection and infection. Since autologous fascia was one of the original graft materials utilized in pelvic floor repair, there is longer term data to suggest that the grafts provide durable results. A recent retrospective review was performed on 303 women who underwent autologous and cadaveric grafts over a nine-year period with a minimum 12-month follow-up. The results showed higher rates of recurrent leakage and reoperation for stress urinary incontinence (39.6% vs. 28.3% and 12.7% vs. 3.3%, respectively) following the use of cadaveric versus autologous fascia.\[4\] However, the use of autologous materials was associated with increased pain, risk of hernia formation at the harvesting site and increased operative time. Nevertheless, both allografts and autografts can be of variable quality depending on the patient’s age and associated medical conditions.

**Allografts**

Because of the potential morbidity associated with harvesting autologous fascia, the use of allograft tissue can be a desirable alternative. Human tissue procured from cadavers is harvested within 24h of death and is cultured and processed to reduce potential risk of disease transmission. The graft materials most commonly used include cadaveric fascia lata and dermis. Processing techniques to sterilize and prepare these tissues include irradiation, freeze-drying or solvent dehydration. The different processing techniques can affect the integrity of the grafts, which is a potential disadvantage with cadaveric materials; however, the discussion of the biomechanics of the allograft tissues is beyond the scope of this manuscript. Despite these techniques, there is still a remote risk of 1/1,667,600 for transmission of human immunodeficiency virus and a theoretical risk of prion transmission. Porcine SIS and dermis are processed to remove cellular components, leaving only collagen and elastin fibers that do not elicit an immune response. This allows for remodeling of the sling by host tissue.\[10\] \[12\] Two separate prospective randomized studies comparing porcine dermal pubovaginal sling to the tension-free vaginal tape (TVT), which utilizes a synthetic polypropylene mesh, showed similar cure rates of 89% and 85% at a median follow-up of 12 months and 82.4% and 88.3% at a median follow-up of 36 months.\[13\] \[14\] Xenografts are costly and long-term data is still lacking. Table 3 lists the extrusion rates reported in some allograft series.

**Xenografts**

Xenografts such as porcine dermis and small intestinal submucosa (SIS) provide other biograft alternatives. These materials offer potential advantages over allografts in that they are more readily available and there is no theoretical risk of human viral transmission. Porcine SIS and dermis are processed to remove cellular components, leaving only collagen and elastin fibers that do not elicit an immune response. This allows for remodeling of the sling by host tissue.\[10\] \[12\] Another review of 69 patients who underwent pelvic repair using dermal allograft material was performed by Drake et al who noted a 10.9% vaginal extrusion rate. All cases were managed expectantly and with vaginal estrogen cream and all resolved spontaneously.\[8\] Others, including the authors, have had favorable experience with conservative management of cadaveric fascial extrusion and do not believe that formal surgical excision is generally necessary. This review does not provide an exhaustive analysis of all biograft studies; however, Table 2 lists the extrusion rates reported in some allograft series.

**SYNTHETIC MATERIALS**

Synthetic materials may have some advantages over biologic materials in terms of disease transmission, durability, tensile strength and availability.\[10\] The types of mesh are categorized based on pore size and fiber type as originally described for their use in abdominal wall hernia repairs.\[15\] While the advantages of using synthetics for vaginal surgery are evident, there are specific concerns regarding their use. This includes complications associated with the surgical procedure itself such as bleeding, hematoma formation, bladder and bowel injury,
Table 2: Erosion/extrusion rates for various allografts[9,39-41]

| Graft Study | No. patients (repair) | No. Erosion/extrusion (%) | Description of erosion/extrusion | Management |
|-------------|----------------------|---------------------------|----------------------------------|------------|
| Dermal allograft | Clemons et al (2003) | 33 (anterior) | 0 (0%) | Vaginal extrusion (3 anteriorly, 4 posteriorly) | Conservative with topical estrogen cream. All experienced spontaneous resolution |
| Drake et al (2005) | 69 (21 anterior, 45 posterior, 3 both) | 7 (10.9%) | | |
| Allograft fascia lata | Flynn et al (2005) | 24 (sacrocolpopexy) | 0 (0%) | Intravaginal granulation tissue caused by extrusion of panacryl sutures used for the cystocele repair and vault suspension | Patients treated by suture removal and fulguration of the granulation tissue with silver nitrate |
| Frederick et al (2005) | 251 (cadaveric prolapse repair with sling (CaPS)) | 22 (9%) | | |

Table 3: Success and complication rates of various xenografts[11,12,42-44]

| Graft Study | No. patients (repair) | Cure rate | Complications |
|-------------|----------------------|-----------|---------------|
| Porcine Gomelsky et al (2003) | 70 (cystocele) | 91% | 12.9% recurrent cystocele at a mean follow-up of 24 months |
| Giri et al (2006) | 48 (pubovaginal sling) | 54% | 1 urethrolysis, 1 suprapubic wound infection, 1 urinary tract infection, 2 vaginal bleeding, 2 pain during intercourse, 2 deep pelvic pain |
| Porcine small intestinal submucosa | Jones et al (2005) | 34 (mid-urethral sling) | 79% | 9% developed suprapubic inflammation |
| Rutner et al (2003) | 152 (pubovaginal sling with bone anchors) | 93.4% | 4.6% recurrent stress urinary incontinence |
| Ho et al (2003) | 10 (pubourethral sling) | 90% | 60% - six patients presented with postoperative inflammatory reactions |

adhesions and obstructive ileus and complications from the material itself, including infection, urinary tract erosion and vaginal extrusion, sinus-tract formation and abscess formation. In addition, functional problems may arise including de novo urgency, urge incontinence and urinary.[16,17] Table 4 lists the properties of the various synthetic materials available and their use in pelvic reconstruction.

**Type I mesh**

Type I meshes have a pore size of >75 mm, which is considered macroporous. They are composed of polypropylene monofilaments. The large pores allow access for leukocytes and macrophages, as well as ingrowth of fibroblasts and collagen and neovascularization. All this contributes to lower infection rates and promotes tissue incorporation into the host.

**Type II mesh**

Type II meshes have a pore size of <10 mm and include a multifilament expanded polytetrafluoroethylene mesh that only allows passage of histiocytes. There is therefore minimal incorporation into host tissue.

**Type III mesh**

Type III meshes are braided or multifilamentous with both macroporous and microporous components.

**Type IV mesh**

Type IV meshes have a submicronic pore size of <1 mm. Due to the sheet-like material that has poor tissue incorporation, this mesh is not often used in vaginal reconstruction. One exception is the polyethylene terephthalate fabric coated with silicone that has large pores with some submicronic components as well.[18]

**EROSION AND EXTRUSION**

For the purpose of this paper, we define “erosion” as the presence of graft material in the lumen of the urinary tract and “extrusion” as the presence of exposed graft material in the vagina.

Use of Type I mesh has demonstrated consistent success with similar rates of vaginal extrusion regardless of the technique for placement. Extrusion rates of 0.4-4.8% for TVT, 1-10.5% for SPARC and 0-6.7% for the transobturator Monarc have been reported.[19-23] A second transobturator sling that utilized a fusion-welded, thermally bonded, nonwoven, nonknitted polypropylene mesh (Ob-Tape™, Mentor Corp, Santa Barbara, CA) had significantly higher rates of extrusion ranging from 10-20%.[22,24-26] Comparable extrusion rates of 0-19% have been reported with sacrocolpopexy.[27,28] New techniques (Apogee™ and Perigee™ (American Medical Systems, Minnetonka, MN) and Gynecare Prolift™ (Ethicon, Sommerville, NJ) have been developed that place polypropylene via the transobturator
Nazemi, et al.: Complications of grafts used in female pelvic floor reconstruction

or transvaginal approach in the repair of anterior vaginal wall prolapse or vaginal vault prolapse. These techniques have shown promising early results, but intermediate and long-term data on rates of erosion and extrusion are yet to be presented. 

Table 4: Properties of synthetic materials

| Mesh type | Pore size | Structure | Synthetic material | Trade name | Use in pelvic floor reconstruction |
|-----------|-----------|-----------|--------------------|------------|----------------------------------|
| I         | >75 µm    | Monofilament | Polypropylene   | Uretex® Self-Anchoring Urethral Support System (CR Bard, Haverhill, RI) | Transvaginal |
|           |           |           |                   | Uretex® TO Trans-Obturator Urethral Support System (CR Bard, Haverhill, RI) | Transobturator |
|           |           |           |                   | Gynecare TVT (Ethicon/Johnson and Johnson, Somerville, NJ) | Transvaginal |
|           |           |           |                   | Gynecare TVT-O (Ethicon/Johnson and Johnson, transobturator) | Inside-out |
|           |           |           |                   | SPARC® Self-fixating Sling System (American Medical Systems, Minnetonka, MN) | Suprapubic |
|           |           |           |                   | In-Fast™ Ultra Transvaginal Sling (American Medical Systems, Minnetonka, MN) | Transvaginal with bone anchors |
|           |           |           |                   | Monarc™ Subfascial Hammock (American Medical Systems, Minnetonka, MN) | Transobturator |
|           |           |           |                   | Lynx® Suprapubic Mid-Urethral Sling System (Boston Scientific, Natick, MA) | Suprapubic |
|           |           |           |                   | Advantage® Transvaginal Mid-Urethral Sling System (Boston Scientific, Natick, MA) | Transvaginal |
|           |           |           |                   | Obtryx® Transobturator Mid-Urethral Sling System (Boston Scientific, Natick, MA) | Transobturator |
|           |           |           |                   | T-Sling (Caldera Medical, Augura Hills, CA) | Suprapubic, transvaginal or transobturator approach |
|           |           |           |                   | Aris™ Trans-obturator Tape (Mentor Corp, Santa Barbara, CA) | Transobturator anterior prolapse repair |
|           |           |           |                   | Perigee™ (American Medical Systems, Minnetonka, MN) | Transvaginal vaginal vault prolapse repair |
|           |           |           |                   | Apogee™ (American Medical Systems, Minnetonka, MN) | Transvaginal vaginal vault prolapse repair |
|           |           |           |                   | Gynecare Prolift (Ethicon/Johnson and Johnson, Somerville, NJ) | Variable use |
|           |           |           |                   | Prolene (Ethicon/Johnson and Johnson, Somerville, NJ) | Variable use |
| II        | < 10 µm   | Multifilament | Expanded PTFE | Gore-Tex® (W. L. Gore, Flagstaff, AZ) | Sacrocolpopexy, suprapubic, transvaginal |
| III       | < 10 µm   | Multifilament | Expanded PTFE | Teflon (CR Bard, Haverhill, RI) | Sacrocolpopexy, suprapublic, transvaginal |
|           |           |           | PTFE | Gore-Tex® (W. L. Gore, Flagstaff, AZ) | Suprapubic, transvaginal |
|           |           |           | PTFE | Teflon (CR Bard, Haverhill, RI) | Transobturator |
|           |           |           | Polyethylene | Mersilene (Ethicon/Johnson and Johnson, Somerville, NJ) | Sacrocolpopexy, suprapublic, transvaginal |
|           |           |           | terephthalate | IVS Tunneller™ (Tyco Healthcare, Norwalk, CT) | Transvaginal |
|           |           |           | Polypropylene | Obturator IVS Tunneller™ (Tyco Healthcare, Norwalk, CT) | Transobturator |
|           |           |           | Woven polyester | ProteGen (Boston Scientific, Natick, MA) | Recalled 1999 |
|           |           |           | Silicone-coated polyester | Intemesh (American Medical Systems, Minnetonka, MN) | Sacrocolpopexy, suprapublic, transvaginal |
|           |           |           | Dura mater substitute | PRECLUDE® MVP® Dura Substitute (W. L. Gore, Flagstaff, AZ) | Transobturator |
|           |           |           | Expanded PTFE, pericardial membrane substitute | PRECLUDE® Pericardial Membrane (W. L. Gore, Flagstaff, AZ) | Suprapublic, transvaginal |

Adapted from Karlovsky et al. 2005. [6]

Type II and III meshes are multifilamentous and therefore may allow bacteria to pass through and adhere to the graft and surrounding tissues. The small pore size does not allow passage of macrophages and leukocytes that may counter invading bacteria. It is because of these theoretical issues that
Type II and III meshes are now rarely, if ever, used in pelvic floor reconstruction. Similarly, Type IV mesh has pore sizes too small to allow for fibroblast and leukocyte infiltration. They tend to induce pseudocapsules that may harbor infection. High rates of erosion, extrusion and other complications were noted and subsequently, Type IV mesh is rarely used in pelvic reconstructive surgery [Figure 1].[18]

Table 5 lists reported extrusion and erosion rates for Type II, III and IV meshes.

**RISK FACTORS**

As discussed previously, erosion or extrusion of the mesh is thought to be associated with the type of synthetic material used. However, patient factors such as poorly controlled diabetes mellitus, tobacco use, prior history of pelvic irradiation, repeat procedures and vaginal estrogen status may also contribute to poor wound healing and subsequent infection, erosion or extrusion. Some studies have suggested that concomitant hysterectomy may be an additional risk factor for extrusion of the sacrocolpopexy mesh.[28,31] Surgical techniques such as excessive tension and unrecognized urethral or vesical injury may also contribute to higher rates of urinary tract erosion.[32] In addition, rolling of the tape during placement or vaginal suturing may produce a narrow band that can result in pressure necrosis and erosion.[20]

While repairs requiring greater dissection tend to have higher rates of complications, the placement of slings via the transvaginal versus transobturator route do not appear to play a significant role in the risk of erosion or extrusion in the literature available to date. Prospective randomized trials that compare sling placement techniques are currently in progress.

**DIAGNOSIS AND MANAGEMENT**

Patients who present with vaginal extrusion or urinary tract erosion may demonstrate a variety of symptoms, but they may be completely asymptomatic. Usual presenting symptoms include vaginal discharge, pain, dyspareunia, complaints of pain from the partner during intercourse, *de novo* stress urinary incontinence, urgency, hematuria or urinary tract infection or obstruction. In the experience of the authors, physical exam findings can usually identify extrusion of mesh components on pelvic exam. However, in cases of high suspicion without visualization of extruded mesh, exam under anesthesia may be necessary. It is of utmost importance to evaluate the urinary tract with cystourethroscopy to rule out erosion of material into the bladder or urethra, particularly if the patient presents with hematuria, recurrent urinary tract infections, irritative or obstructive symptoms, *de novo* urgency or bladder stones. In addition, we have noted from our own experience that over 30% of patients with vaginal extrusions required exam under anesthesia in order to adequately identify their extrusion sites, demonstrating the importance of a high index of suspicion for extrusion in those with clinical indications.

| Mesh type | Material | Trade name | Study | No. patients | No. erosion/extrusion (%) | Description of complication |
|-----------|----------|------------|-------|--------------|--------------------------|-----------------------------|
| II Expanded | PTFE     | Gore-Tex® (W. L. Gore, Flagstaff, AZ) | Choe *et al* (1999) | 90 | 5 (5.6) | Vaginal granulation requiring removal of mesh |
|           |          |            | Begley *et al* (2005) | 33 | 3 (9) | Vaginal extrusion |
|           |          |            | Weinberger *et al* (1995) | 98 | 25 (26) | Ten vaginal extrusions, ten granulation tissue, five sinus tracts |
| III PTFE  |          | Teflon (CR Bard, Haverhill, RI) | Yamada *et al* (2001) | 137 | 1 (0.7) | Urethral erosion |
|           |          |            | Nygaard *et al* (2004) | 119 | 6 (5.5) | Mesh erosion or extrusion following sacrocolpopexy |
|           |          | Mersilene (Ethicon/Johnson and Johnson, Somerville, NJ) | Young *et al* (2001) | 176 | 8 (4) | Seven vaginal and one inguinal sling erosion |
|           | Polyethylene terephthalate |          | Kohli *et al* (1998) | 10 | 2 (20) | Vaginal extrusion |
|           | Polypropylene | IVS Tunneller™ (Tyco Healthcare, Norwalk, CT) | Siegel *et al* (2005) | 35 | 6 (17%) | Vaginal extrusion |
|           | Woven polyester | ProteGen (Boston Scientific, Natick, MA) - recalled 1999 | Kobashi *et al* (1999) | N/A | 34 | Vaginal extrusion, infection or pain all requiring removal |
| IV Silicone-coated polyester |           | Intemesh (American Medical Systems, Minnetonka, MN) | Begley *et al* (2005) | 21 | 4 (19) | Vaginal extrusion |
|           |          |            | Duckett *et al* (2000) | 7 | 5 (71) | Vaginal extrusion and sinus formation |
Management is based on the type of material, presence of infection and location of erosion or extrusion. From our own experience and from review of the literature, we have found that extrusion of Type I polypropylene mesh into the vagina may be managed conservatively with abstinence from sexual intercourse, local estrogen replacement therapy and antibiotics if associated infection is noted.\(^1,\)\(^{33}\) The clinician should counsel the patient on the possible length of healing time (six to eight weeks) as some patients may prefer to proceed with definitive treatment rather than abstaining from intercourse for this length of time. Spontaneous healing rates from 29-100\% have been reported with conservative management.\(^1,\)\(^{33}\) One group described 26\% cure rate with abstinence and local vaginal antiseptics for one month.\(^3\)\(^1\)\(^3\) If these measures fail after six to eight weeks, then excision of the exposed mesh with adequate debridement of underlying and surrounding tissues will allow for improved wound healing.

Persistent infection or failure to epithelialize over a type I mesh warrants complete mesh excision [Figure 2]. The approach to removal of the mesh is often mandated by the location of the mesh. In general, pubovaginal, transobturator and transvaginal slings may be removed transvaginally and mesh placed for sacrocolpopexy should be removed abdominally. If complete removal of extruded mesh via the transvaginal route is not feasible, then transabdominal approach may be indicated for the retropubic slings. Transobturator slings, when associated with infection, may require exploration of the thigh in extreme cases.

Vaginal extrusion of type II, III and IV meshes generally requires complete excision due to higher risks of infection and poor healing rates. As with type I mesh, excision may be performed transvaginally if the exposed graft can be removed completely with adequate debridement and reapproximation of vaginal epithelium.\(^3\)\(^0\) Ironically, the mesh types that induce pseudocapsule formation tend to be easier to remove than the type I meshes that allow extensive tissue regrowth.

Erosion into the urinary tract mandates complete removal of mesh regardless of mesh type [Figure 3]. Erosion of mesh into the bladder is rare and has traditionally been excised using a transvesical approach. Patients often present with hematuria, irritative voiding symptoms, urinary tract infection or retention. Cystoscopic resection of intravesical materials has been reported by Clemens et al. Of 14 patients that presented with complications following pubovaginal sling placement, two were noted to have erosion of mesh into the bladder and both were managed by endoscopic sling and/or suture removal. At one month follow-up, both patients’ symptoms had resolved and both were continent.\(^3\)\(^4\) One must use caution to remove as much mesh as possible when using a cystoscopic approach as the retained mesh may continue to erode and potentiate symptoms.

Urinary tract erosion of mesh that has been used in sacrocolpopexy may be addressed via laparoscopy or laparotomy with retroperitoneal graft excision.

Urethral erosions require urethrolysis with graft explantation.
Urethral debridement followed by primary repair and multilayer closer with a Martius flap has been described by Amundsen et al. In a review of nine patients who presented with erosion of graft material into the urethra, three were from synthetic grafts that were excised and repaired as described. At a mean follow-up of 30 months, no urethral erosion or fistulas occurred, however, stress incontinence recurred in two of the three patients.[32] Clemens et al recommend urethral catheter drainage for two weeks with a pull-out cystourethrogram at the time of catheter removal.[34]

Newer techniques have been described in the treatment of mesh extrusion and erosion. Laparoscopic excision of mesh associated with bladder erosion and transvaginal endoscopic removal of mesh after sacrocolpocomy have been described.[35,36] Pikaart et al report three patients with mesh noted in the bladder following pubovaginal placement of polypropylene mesh tape. All three underwent successful laparoscopic removal of the mesh and at six months follow-up, two of the three patients continued to have complaints of stress and urge incontinence without further mesh erosion into the bladder.[36] Romero et al describe three cases of vaginal mesh extrusion following abdominal sacrocolpocomy treated by transvaginal endoscopic excision of mesh. All three patients continued to have excellent support with adequate tissue healing at follow-up (six weeks to one year).[35] A technique of cystoscopic excision using a suprapubic port to excise the mesh has also been described by Rosenblatt et al. Two cases of bladder erosion following TVT were managed using cystoscopic excision combined with traction from laparoscopic graspers through a small suprapubic port. One of the patients had follow-up office cystoscopy at six weeks that showed appropriate resolution with no persistent mesh in the bladder.[37]

Continenence rates following mesh removal have been variable and often dependent on the amount of dissection performed and presence of infection. Reported rates of continence have ranged from 42-100%.[20,34,38]

CONCLUSIONS

Synthetic mesh has become a popular option for pelvic reconstruction. The potential complications of urinary tract erosion and vaginal extrusion are dependent on multiple factors including mesh type and patient tissue integrity. However, review of short and intermediate term data from the literature has shown that amongst synthetic grafts, type I mesh provides durable results with the fewest rates of erosion and extrusion. In addition, viable management options for vaginal extrusion include conservative approaches such as observation with or without local estrogen administration. While all materials, synthetic and biologic alike, have advantages and disadvantages in the treatment of pelvic floor disorders, synthetic materials may provide a safe and cost-effective alternative for pelvic reconstructive surgery.

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