Published in final edited form as:
Am J Obstet Gynecol. 2008 December ; 199(6): 688.e1–688.e5. doi:10.1016/j.ajog.2008.07.029.

Risk Factors for Mesh/Suture Erosion Following Sacrocolpopexy

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Abstract

Objectives—To identify risks for mesh/suture erosions following sacrocolpopexy (ASC).

Study Design—We analyzed demographic, perioperative variables and erosion status in 322 participants in the Colpopexy and Urinary Reduction Efforts study two years after sacrocolpopexy.

Results—The predominant graft used was synthetic mesh; Mersilene (42%) or Polypropylene (48%). Twenty subjects (6%) experienced mesh/suture erosion. Unadjusted risk factors for mesh/

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To be presented at: **34th Annual SGS Scientific Meeting**, Monday-Wednesday, April 14-16, 2008, Westin Savannah Harbor Golf Resort & Spa, Savannah, Georgia

Reprints will not be available.

Condensation Gore-Tex® mesh, concurrent hysterectomy, and current smoking are risk factors associated with mesh/suture erosion complications following sacrocolpopexy.

suture erosion were expanded polytrafluroethylene (ePTFE) mesh (ePTFE 4/21 (19%) versus non-ePFTE 16/301 (5%): OR 4.2), concurrent hysterectomy (OR 4.9) and current smoking (OR 5.2). Of those with mesh erosion, most affected women (13/17) underwent at least one surgery for partial or total mesh removal. Two were completely resolved, 6 had persistent problems and 5 were lost to follow-up. No resolution was documented in the 4 women who elected observation.

Conclusions—Expanded PTFE mesh should not be used for sacrocolpopexy. Concurrent hysterectomy and smoking are modifiable risks for mesh/suture erosion.

Keywords

Expanded polytrafluroethylene (Gore-TexR®); Mesh Erosion; Sacrocolpopexy; CARE Trial; hysterectomy

Introduction

Abdominal sacrocolpopexy (ASC) is a commonly performed procedure for the surgical treatment of apical pelvic organ prolapse. Surgeons who favor this technique rely on its well-established success rates ranging from 78-100% and durability, which is attributed to reinforcement of native tissues with a graft. [1] Despite recognition of the risk of erosion, synthetic graft materials have been preferred over autologous grafts for ASC because they are durable, avoid the morbidity and operative time of harvesting fascia, are readily available and are relatively inexpensive. Ideally, these benefits should outweigh the possibility of erosion, a unique complication of using a graft.

Sacrocolpopexy mesh erosion is typically evident by exposure of the graft in the vagina. In such cases, granulation tissue and a sero-purulent or sero-sanginous discharge is usually present. This may be accompanied by pain or tenderness and dyspareunia. [2] Occasionally the sacrocolpopexy vaginal sutures may be the only visible foreign material. In the absence of visible graft, some investigators prefer the term suture erosion.

The pathophysiology of these materials complications is not known and not implied by the word “erosion”, used here to indicate an unplanned exposure of surgical materials. Erosion may result from an inflammatory reaction due to infection of the foreign body or, possibly, due to an immunological response to the graft or suture material. Alternatively, the mesh or sutures may be exposed without an obvious inflammatory reaction and can be relatively asymptomatic. Nevertheless, the management of erosions has a significant occurrence of major complications.[3,4]

A recent sacrocolpopexy literature review reported a median rate of 3.4% for synthetic mesh erosion, with rates varying depending on which grafts were used (0% with biologic grafts; 0.5% with polypropylene mesh; to 5.5 % with Teflon mesh).[1] No definite conclusions could be made regarding whether specific graft types were more likely than others to predispose recipients to erosion because other variables such as method of graft placement, concurrent hysterectomy, and various demographic differences were infrequently available for analysis. Other reports also link erosion to the type of mesh used and method of placement without identifying other risk factors. [2,5]

The Colpopexy andUrinary Reduction Efforts (CARE) trial provides an excellent opportunity to look for potential risk factors for mesh/suture erosion in a large cohort of well-described patients that underwent a sacrocolpopexy with standardized physical exams at set intervals during the two-year follow-up. Our objective was to identify demographic and surgical parameters associated with foreign body complications of the ASC specifically mesh and suture erosion.

Methods

The CARE trial was a randomized surgical trial of 322 stress continent women with Stages II to IV pelvic organ prolapse conducted to investigate the benefit of an adjuvant Burch colposuspension at the time of sacrocolpopexy. The study was designed and implemented by the Pelvic Floor Disorders Network (PFDN), a consortium of clinical sites and one data management center funded by the National Institute of Child Health and Human Development. Each clinical site and the data-coordinating center received institutional review board approval and all women provided written informed consent. We previously reported the CARE trial methods,[6] three-month outcomes,[7] and global two-year outcomes.[8]

This prospectively planned analysis included baseline, surgical and post-operative outcome data, as well as complication and safety data collected throughout the 2-year postoperative follow-up period. Demographic and medical history data were collected by interview at baseline. Participants underwent the a standardized Pelvic Organ Prolapse Quantification (POP-Q) examination [9] at baseline, the 6 weeks, 3 months, 12 months and the 2-year postoperative visit. A speculum exam to screen for mesh or suture erosion was performed at each post-op visit.

Sacrocolpopexy via laparotomy was the clinically selected surgery whereas the Burch colposuspension was the research procedure in the CARE trial. Therefore, the study permitted variations in ASC technique that were not thought to influence the primary and secondary outcomes. Such variations included the type of laparotomy incision and configuration of the graft (recorded as conical, two-strap, Y, fingered or other configurations. Selected graft and sutures material (from a list generated during study inception that reflected their common clinical practice) included autologous tissue (such as rectus fascia or fascia lata), synthetic material including woven polyester, (Mersilene™, Ethicon Inc, Sommerville NJ), polypropylene (, Prolene™ Ethicon Inc, Sommerville NJ), soft weave polypropylene (Gynemesh ™ Ethicon Women's Health & Urology, Cincinnati) and expanded polytrafluroethylene (ePFTE) (Gore-Tex®, GORE™ Medical, Newark DE) or Trelex™), allograft material (such as cadaveric rectus fascia or fascia lata) and xenograft material such as hexamethylene diisocyanate cross-linked porcine dermis (Pelvicol ™ CR BARD, Murray Hill, NJ). Synthetic absorbable material (such as polygalactin mesh) was not allowed.

Graft material was sutured to both the anterior and posterior vaginal walls and then anchored to the anterior longitudinal ligament of the sacrum in such a way as to avoid tension on the anterior portion of the graft. A minimum of two stitches was used to secure the graft material to the sacrum. The type, gauge and number of stitches used on the vaginal and sacral ends of the grafts were recorded and characterized as interrupted or continuous. Other technical aspects of the sacrocolpopexy procedure, including performance of concurrent procedures for anterior and posterior prolapse, culdoplasty, and reperitonealization were left to surgeon preference but were recorded. Because of the potential impact on the primary outcome, stress incontinence, subjects were stratified by the intent to perform a paravaginal repair (done at the surgeon's discretion and disclosed before randomization) as well as by surgeon.

Adverse events forms were completed for each episode of mesh or suture erosion and were updated after any procedure or treatment for this complication. All adverse event (AE) forms were completed and signed by the study surgeon who assigned intensity, causality with respect to study surgery or concomitant procedures and outcome or resolution. The DCC generated regular reports for the Data Safety and Monitoring Board (DSMB). In

February 2005, the DCC noted that 4 of the first 5 reports of mesh/suture erosions were received from 3 study surgeons who were using ePTFE in combination with a second material for graft material. Based on safety concerns, the Data Safety Monitoring Board mandated that the use of ePTFE mesh be discontinued for future CARE participants. For this analysis, two surgeon authors reviewed all foreign body adverse events inclusive of surgical reports to confirm the nature of the surgical material complication, treatment and last known status.

The groups were compared at baseline by age, body mass index (BMI), and prolapse stage; subsequent analyses were not adjusted for these measures since they were similar in both groups. Fisher's exact test is used to compare the proportion of erosions in those with a specific material to the proportion of erosions in those not using the material; all p-values are two-tailed. For certain data elements, totals are less than the entire sample size as not all subjects provided completed data. Results are presented as percentages or as mean ± standard deviation (SD); odds-ratios and their 95% confidence intervals are also presented.

Results

The original CARE cohort included 322 women who underwent sacrocolpopexy, 157 randomized concomitant Burch colposuspension and 165 to no Burch colposuspension. Most (93%) of the CARE participants completed aspects of the two-year assessment, and the non-completers did not differ significantly from completers. However, 74 (23%) did not undergo a pelvic examination at 24 months. Most participants were Caucasian (93%) with a mean age of 61±10 years (mean±SD). The majority of subjects (74%) were married and parous with a median parity of 3. The mean BMI was 27±4.5 kg/m^2 and most had a BMI <30 (77%). Socioeconomic indicators, including level of education and type of medical insurance, were widely distributed. Table 1 presents other demographic characteristics of the sample.

There were 20 (6%) mesh/suture erosions reported within two years of surgery. Three of the erosions involved suture only, while 17 had exposed mesh. The mean interval from surgery to erosion was 313 days (range 45-744). Current smoking was more common in subjects with mesh/suture erosion [5/20(25%) versus 18/302 (6%), OR 5.2 (CI 1.7, 16.0), p=0.009]. There were no other statistically significant demographic differences between subjects with and without mesh/suture erosion, including estrogen status (premenopausal/replacement therapy use) (p=0.24), diabetes (p=0.07), or prior surgery for prolapse (p=0.10).

Concurrent hysterectomy was performed in 83/322 (26%) of subjects, and was more common in the group with mesh/suture erosion [60% versus 24%, OR 4.9 (CI 1.9, 12.4), p=0.0009]. There was no difference in the erosion rate based on the randomized intervention, Burch colposuspension. We did not detect an effect of mesh configuration on mesh/suture erosion either (p=1.0). Some form of culdoplasty was used in 112 (35%), with the Halban technique being most common, and no detected difference among erosion groups. There was also no statistical difference in operating time, estimated blood loss, or intraoperative and postoperative complications.

Surgeons used a variety of graft and suture materials for the ASC (Table 2). Most ASC procedures were done with synthetic mesh (92%) with common use of woven polyester (42%) and polypropylene (48%) and minimal use of ePFTE (6%); some were used in different combinations. Despite the small number of participants exposed to ePFTE, we detected a significantly higher risk of mesh erosion in women who had ePFTE mesh (alone or in combination) compared to those without ePFTE mesh [4/21 (19%) versus 16/301 (5.3%), OR 4.2 (95% CI 1.3, 13.9), p=0.033]. A minority of subjects received two types of

grafts 25(8%), including 9(2.8%) ePTFE/polypropylene, and 7(2.2%) ePTFE/braided polyester. The use of ePFTE for combined graft was also associated with mesh/suture erosion (4/17, (24%) versus 16/305, (5.2%): OR 5.6 (95% CI 1.6, 19.0)).

A wide variety of sutures were used for attachment of the grafts to the vaginal walls and anterior longitudinal ligament of the sacrum. The mean number of sutures used for the vaginal attachment of both grafts was 12.7 with a range of (4-22), with ePFTE suture used most commonly for anchoring the graft to the vagina (53%). There were no associations of mesh/suture erosion with polypropylene or polyester and while there was a trend for higher rate of erosion with ePFTE, it was not statistically significant. (Table 2)

Two of three patients with suture erosions healed after simple removal of suture. The third patient probably had suture erosion, but healing after suture removal has not been confirmed. Of the remaining events, 17 were mesh erosions; 4 were managed without surgery, of which 1 was lost to follow-up and the other 3 had no resolution. Thirteen patients with mesh erosion underwent at least one surgery, for mesh removal. Two patients had resolution, 6 had persistent erosions and 5 were lost to follow-up. One subject had two partial resection procedures and one had three; both had subsequent chronic sinus tracts.

Comment

In our prospective study with standardized follow-up, 20 of 302 (6% CI 4.0 – 9.5%) of subjects had mesh or suture erosion. This is higher than the 3.4% rate (70 of 2178) of mesh erosions reported in a comprehensive literature review by Nygaard et al[1], but nearly the same as the 8% rate reported in another large case series of 92 ASCs.[5] Neither of these reviews included suture erosions. In this analysis, we included all patients with either suture or mesh exposures, including participants who responded to non-surgical treatment of the erosion.

The most important finding of our study is that there are modifiable surgeon and patient risk factors that are associated with an increased risk of mesh or suture erosion. The risk of mesh complications was nearly four-fold higher if ePTFE (Gore-Tex®) mesh was used compared to a non- ePTFE mesh, a strong association that was noted early on in the study and altered ePTFE use. Although only 6% of patients had their ASC performed with ePTFE material, the 4-fold association was significantly strong and clinically relevant. Recent literature supports our results. Begley et al [5] found high rates of colpopexy mesh erosion with ePTFE (9%) and silicon coated mesh (19%) and a single center recently reported that 15 of 22 referred ASC mesh erosions were ePTFE.[10] Mesh erosion rates are even higher if ePTFE is placed transvaginally; in a series of 108 ePTFE vaginal slings, Weinberger et. al reported a 40% infection rate and 22% removal rate [11]. ePTFE mesh has been used extensively in abdominal hernia repairs and has several unique qualities. The material is microporous; this reduces host tissue ingrowth and adhesion formation, which is why ePTFE can be safely placed in direct contact with the intestines. We do not fully understand the etiology of mesh erosion, however, infection may be a contributing factor. The qualities of ePTFE mesh reduce the accessibility of micro-organisms to antimicrobial agents and the host immune system and can create a bacterial sanctuary. Therefore, when ePTFE becomes infected, treatment nearly always requires the removal of the entire mesh.[12] During a ASC, the mesh is placed abdominally under sterile conditions, but the sutures that secure the mesh to the vagina may traverse the full thickness of the vagina and vaginal bacteria may travel along the suture to colonize the mesh. This risk of bacterial ascension may be greater with multifilament vaginal sutures although our study does not have sufficient power to conclusively support or refute this theory.

Concurrent total abdominal hysterectomy was performed in 26% of our subjects and these subjects had a 14% risk of erosion compared to just 4% in women who had a previous hysterectomy and, therefore, had their colpopexy performed on an intact vaginal cuff. This five-fold increased risk of erosion with concomitant hysterectomy is consistent with data from a retrospective review of 313 women which found a statistically significant 5-fold risk in women on estrogen with concomitant hysterectomy.[13] In cases of mesh erosion with concomitant hysterectomy the erosion site is nearly always at the cuff. Two theories may explain this result. The first theory is that there is increased vaginal bacterial contamination of the mesh from an opened vagina during hysterectomy. The second theory is that poor healing occurs at the new cuff because of the devascularizing effects of both cuff closure and mesh vaginal attachment sutures. For this reason, some surgeons prefer performing supracervical hysterectomies and sacrocolpocervicopexies when hysterectomy is indicated and normal cervical cytology has been documented.

Smoking was also associated with a five-fold increased risk of erosion and is a patient modifiable risk factor. In a recent retrospective ASC study of 21 mesh erosions seen in 499 women there was a non-significant trend for smokers to require more than one surgery for effective treatment of their erosions.[3] It is possible that microvascular vasospasms associated with smoking lead to poor wound healing and vaginal mesh erosion.

Our study was not powered to analyze management of erosions and clinical decisions varied depending on the patient's clinical presentation. Anecdotally, when only a small area of the graft is exposed without obvious inflammatory response, a trial of transvaginal estrogen is frequently advocated to stimulate growth of the vaginal mucosa over the exposed area. There is minimal literature evaluating this approach, although the available evidence only notes a 14% cure.[14] Exposed sutures may be removed in the exam room. Larger areas of exposed mesh and any erosion with an obvious inflammatory reaction thought limited to the area of vaginal attachment may be managed by local surgical excision, however anesthesia is generally indicated to evaluate the extent of the mesh involvement and to allow for whatever surgical excision and debridement is deemed necessary. This approach has a reported efficacy of 50%.[3] When the upper portion of the mesh is infected, removal of the entire graft is required through either a transvaginal or abdominal approach. Residual infected mesh after a failed partial excision requires a second excision generally via laparotomy, and usually represents a difficult surgical dilemma as recurrent erosions are associated with chronic morbidity including chronic infection, sinus tracts, abscess and fistula formation.[3,13]

The strength of this study is that it was prospectively designed to capture surgical and mesh/suture erosions at regular study intervals for the first two years. We are confident that few if any mesh erosions were not detected in women who were not lost to follow-up, although it is possible that the 74 patients that did not have a 2-year exam could have had asymptomatic erosions. In fact, many of these 74 subjects did have subjective follow-up by phone, and 3 of the documented erosions were in the group without 24 month exam. Nevertheless, all of the identified risk factors for erosion were more common in the group without a 24 month exam then in the entire sample: smoking 11% v. 7%, concurrent hysterectomy 32% v. 26%, and use of Gortex mesh 9% v. 6%. In fact, a third of the subjects that had Gortex mesh did not have a 24 month exam. Consequently, it is possible that we underestimated the association of these parameters with mesh erosion. We did not randomly assign different types of mesh material in our study, so we cannot exclude the possible confounding effects of surgeon or patient selection bias. However, the statistically significant associations of ePTFE mesh, concomitant hysterectomy, and smoking were strong ones with odds ratios ranging from 4 to 5 and we feel confident in these associations; but as with all retrospective associations, this does not prove causation.

In summary, ePFTE mesh should not be used when performing ASC. Concurrent hysterectomy and smoking are modifiable risks for mesh/suture erosion.

Acknowledgments

Supported by grants from the National Institute of Child Health and Human Development (U01 HD41249, U10 HD41268, U10 HD41248, U10 HD41250, U10 HD41261, U10 HD41263, U10 HD41269, and U10 HD41267).

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Table 1

Selected demographic and surgical variables of subjects undergoing colpopexy (n=322)

		n (%)
Diabetes		16 (5.0%)
Smoking	Current	23 (7.2%)
Estrogen status	Premenopausal/ERT	162 (50.9%)
	Postmenopausal	156 (49.1%)
Prior Surgery for Incontinence		22 (6.8%)
Prior Surgery for Prolapse		126(39.1%)
POP-Q Stage***	Stage II	44(13.7%)
	Stage III	217(67.4%)
	Stage IV	61(18.9%)
Concurrent hysterectomy		83(25.8%)
Prior Hysterectomy		228(70.8%)
Paravaginal repair		61(18.9%)
Culdoplasty	Any	112(34.8%)
	Halban	71(22.0%)
	Moschowitz	24 (7.5%)
Rectocele repair		78(24.2%)
Graft configuration	Conical	12 (3.7%)
	Two strap	182 (56.5%)
	Y configuration	121 (37.6%)
	Fingered	2(0.6%)
	Other	5(1.6%)

Table 2

Graft and suture materials for subjects with and without mesh erosion

		Mesh Erosion N=20	No Erosion N=302	% with Erosion	P-value
Graft	Braided polyester *	10	124	7.5%	0.49
	Polypropylene†	8	148	5.1%	0.49
	Porcine dermis ‡	2	20	9.1%	0.64
	ePTFE#	0	5	0%	1.0
	ePTFE+ synthetic graft	4	12	25.0%	0.012
	Any ePTFE	4	17	19.0%	0.033
Vaginal suture	polypropylene††	2	24	7.7%	0.69
	Braided polyester**	1	37	2.6%	0.49
	ePTFE##	15	157	8.7%	0.063
Suture to sacrum	polypropylene††	0	9	0%	1.0
	Braided polyester**	7	149	4.5%	0.25
	ePTFE##	13	139	8.6%	0.11

* Mersilene ™ Ethicon Inc, Sommerville NJ

† Prolene ™ Ethicon Inc, Sommerville NJ) or Gynemesh ™ (soft weave polypropylene) Ethicon Women's Health & Urology, Cincinnati

‡ Pelvicol ™ (hexamethylene diisocyanate cross-linked porcine dermis) CR BARD, Murray Hill, NJ

Gore-Tex®, GORE™ Medical, Newark DE

†† Prolene™, Ethicon Inc, Sommerville NJ

** Ethibond™, ™ Ethicon Inc, Sommerville NJ

Gore-Tex®, GORE™ Medical, Newark DE