Polypropylene Mesh Predicts Mesh Exposure after Sacrocolpopexy Independent of Known Risk Factors: A Retrospective Case-Control Study

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Sources of support that require acknowledgment: None

Key Words: mesh exposure, sacrocolpopexy, ultra-lightweight polypropylene mesh

Summary Sentence: Heavier weighted meshes increased and monofilament suture decreased mesh exposure rates after sacrocolpopexy

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This is the author's manuscript of the article published in final edited form as:
Durst, P. J., & Heit, M. H. (2018). Polypropylene Mesh Predicts Mesh/Suture Exposure After Sacrocolpopexy Independent of Known Risk Factors: A Retrospective Case-Control Study. Female pelvic medicine & reconstructive surgery, 24(5), 360-366. http://dx.doi.org/10.1097/SPV.0000000000000452

Abstract

Objective(s): Determine if ultra-lightweight polypropylene mesh reduced the risk of mesh exposure after sacrocolpopexy compared to heavier weighted polypropylene

Methods: Bivariate and multivariate analyses were used to interpret data from 133 cases and 261 controls to evaluate independent predictors of mesh exposure after sacrocolpopexy from 2003 to 2013.

Results: Multivariate logistic regression revealed that prior surgery for incontinence (OR 2.87, 95% CI 1.19, 6.96), Porcine acellular cross linked collagen matrix with medium weight polypropylene mesh (OR 4.95, 95% CI 1.70, 14.42), other polypropylene mesh (OR 6.73, 95% CI 1.12, 40.63), non-absorbable braided suture for vaginal mesh attachment (OR 4.52, 95% CI 1.53, 15.37) and immediate perioperative complications (OR 3.64, 95% CI 1.53, 13.37) were independent risk factors for mesh exposure. After multivariate analysis, ultra-lightweight polypropylene mesh was no longer associated with decreased rates of mesh exposure after controlling for known risk factors identified during bivariate analysis (p=0.423).

Conclusion(s): Both mesh choice and suture selection remained independent predictors of mesh exposure with heavier meshes increasing and monofilament suture decreasing rates of mesh exposure. Based on this study, surgeons may consider use of delayed-absorbable, monofilament suture over non-absorbable, braided suture for attachment of vaginal mesh to reduce the risk of mesh exposure when using mesh.

Introduction:

Pelvic organ prolapse (POP) is a common condition affecting approximately 50% of women over the age of 50.[1,2] The prevalence of POP ranges from 2-30%. Samuelsson et al detected a 2% rate of prolapse at the introitus based on physical exam and 30% for any degree of prolapse.[1] This is confirmed by Nygaard et al who detected a 3% rate of symptomatic POP in US women based on an experience of bulging or something falling out of the vaginal area.[2] The number of US women with POP is projected to increase 46% from 3.3 to 4.9 million from 2010 to 2050 as a result of changing demographics.[3] The lifetime risk of any surgical treatment for POP is estimated between 11-19%.[4,5,6] Sacrocolpopexy is a common surgical treatment for POP and is arguably the gold standard in regards to effectiveness due to lower rates of recurrent prolapse.[6-10] While sacrocolpopexy is an effective treatment of POP, it is not without complications; specifically mesh exposure with the introduction of synthetic mesh materials. The historical prevalence of mesh exposure in sacrocolpopexy is 2-10%.[11-16]

Numerous potentially modifiable risk factors have been studied with the aims of reducing mesh exposure rates. Factors that have been associated with mesh exposure include smoking, estrogen status, mesh type, suture type, stage of prolapse, concomitant hysterectomy and additional procedures at time of sacrocolpopexy. The odds ratio (OR) for mesh exposure in smokers ranges from 4.4 to 5.2.[13,14] Estrogen status has been a controversial risk factor with studies that have reported conflicting results.[12,14,17-18] Another controversial risk factor is concomitant hysterectomy. Numerous studies have demonstrated that abdominal, vaginal and laparoscopic-assisted vaginal hysterectomies at time of sacrocolpopexy increase the risk of mesh exposure.[15,19]

Tan-Kim et al reported a 5% rate of mesh exposure in patients with prior hysterectomy or supracervical hysterectomy at time of sacrocolpopexy compared to 23% erosion rate for patients with concomitant TVH or LAVH at time of sacrocolpopexy[15]. Akyol et al showed an increased risk of mesh exposure in patients with concomitant hysterectomy versus prior hysterectomy (47.4% versus 23.8%)[19]. Conversely, conflicting data by Wu, Brizzolara and Marinkovic suggest that concomitant hysterectomy does not increase mesh exposure.[12,20-21] Other identified risk factors include more advanced stages of prolapse (stages III and IV) and performance of more than 3 additional procedures at time of sacrocolpopexy.[19] Additionally, both mesh and suture types have been implicated in higher mesh exposure rates including, silicone and expanded polytrafluroethylene (Gore-Tex®, W.L. Gore & Associates, Flagstaff, AZ) mesh as well as polyester suture (Ethibond®, Ethicon US, Somerville, NJ) respectively.[11,14,22] Type 1 (Amid Classification) knitted, polypropylene mesh has become the preferred choice for sacrocolpopexy because of its biologically inert, structural and biochemical properties. More recently, ultra-lightweight and partially absorbable lightweight materials have been introduced to market with the goal of reducing adverse events associated with synthetic graft implantation. Knowledge of the risk for mesh exposure when these newer synthetic materials are implanted in vivo would provide surgical guidance towards improving outcomes in women with POP while minimizing adverse events.

The aim of our study was to determine if mesh type for sacrocolpopexy was an independent predictor of mesh exposure after controlling for established predictors during bivariate analysis using a case-control design. Specifically, we were interested in determining if ultra-lightweight polypropylene mesh was associated with an increased or decreased risk of mesh exposure

compared to other heavier weighted polypropylene after sacrocolpopexy.

Materials and Methods:

The Institutional Review Board approved this retrospective case-control of sacrocolpopexy mesh exposure at an academic teaching institution from 2003 to 2013. A query of sacrocolpopexy based on CPT codes was performed including all abdominal, laparoscopic and robot-assisted procedures. Sacrocolpopexy cases were cross-referenced with mesh exposure CPT codes during the same time period to create the case list. CPT codes for mesh exposure included all gynecologic mesh exposures. Operative reports for both cases and controls were reviewed to verify type of mesh procedure and allow exclusion of exposures from procedures other than sacrocolpopexy. Cases were defined by the presence of mesh exposure and categorized as exposure of mesh, suture or mesh plus suture. During chart review, any control subjects with exposure of suture or mesh based on documented office exam were added to the case list. A 2:1 control to case list was created by computer-generated randomization of patients who had a sacrocolpopexy without subsequent mesh exposure during the same time period.

Datum was collected on age, body mass index (BMI), smoking status, estrogen status, comorbidities as measured by the Charlson Comorbidity Index, prior procedures for incontinence, prior procedures for prolapse, preoperative leading edge of prolapse, preoperative ICS stage of prolapse, date of sacrocolpopexy, number of additional procedures at time of sacrocolpopexy, length of surgery (skin to skin time), concomitant hysterectomy and type, mesh type, suture type used to close the vaginal cuff, suture type used to attach the mesh to the anterior

and posterior vagina, suture or device used to attach the mesh to the anterior longitudinal ligament, date of last follow up, date of mesh exposure, site of mesh exposure, suture or mesh exposure, type of mesh excision procedure performed, ICS stage at last visit, postoperative leading edge at last visit and immediate and delayed perioperative complications as measured by Clavien-Dindo score and the Comprehensive Complication Index (CCI), respectively. Restorelle® L or M (Coloplast, Minneapolis, MN) with a mesh weight of 19 g/m^2 was considered our ultra-lightweight polypropylene of choice. Ultrapro® (Ethicon US, Somerville, NJ) with a mesh weight of 28 g/m^2 was consider our lightweight polypropylene of choice. Prolene® Soft (Ethicon US, Somerville, NJ) with a mesh weight of 45 g/m^2 was considered our medium weight polypropylene of choice. Other polypropylene that included Atrium™ (Atrium Medical, Hudson, NH) with a mesh weight of 90 g/m^2, and Prolene® (Ethicon US, Somerville, NJ) with a mesh weight of 109 g/m^2 were considered our heavyweight polypropylene of choice.

All procedures were performed by three surgeons in conjunction with residents and urogynecology fellows during the study period. Patients were routinely followed at 6 weeks, 6 months and yearly thereafter independent of mesh exposure status. Surgery type was categorized as follows: mesh augmented apical suspension procedures were categorized as conventional laparoscopic sacrocolpoperineopexy (LSCP) when an abdominovaginal posterior colporrhaphy without levator plication was performed prior to anterior, posterior, apical vaginal and sacral attachment of mesh. The first stage included a vaginal dissection where a traditional posterior colporrhaphy without levator plication was augmented by the overlaid distal LSCP posterior mesh leaflet attached to the iliococcygeal fascia laterally and the perineal body distally. The second stage included attaching the mesh to the posterior vaginal wall laparoscopically in the

standard technique. Procedures were categorized as conventional laparoscopic sacrocolpopexy (LSC) when traditional posterior colporrhaphy without levator plication or no posterior colporrhaphy were performed based on surgeon's examination of the patient's anatomy after apical suspension with anterior, posterior, apical vaginal and sacral attachment of mesh. Surgical technique moved toward minimally invasive approaches over the course of the study with a transition to laparoscopic sacrocolpopexies in 2006. Additionally, graph and suture selection evolved over the course of the study based on the desire to reduce mesh burden for individual patients as lightweight materials became available. If concomitant hysterectomy was performed the vaginal cuff was closed with either vicyrl or PDS suture in a full thickness single layer closure. There were only 5 total laparoscopic hysterectomies where energy was used for the colpotomy.

Exclusion criteria included patients with any mesh exposure from other procedures including tension-free vaginal tape (TVT), transoburator tape (TOT), anterior and posterior colporrhaphy with transvaginal mesh or any other sling, lift or suspension procedures using mesh other than sacrocolpopexy. Cases with more than one type of mesh procedure were examined case by case to review mesh type, suture type and location of mesh exposure to determine inclusion versus exclusion. Sacrocolpopexy revision procedures and subsequent mesh exposures were included.

Our null hypothesis was that ultra-lightweight polypropylene mesh was not associated with either an increase or decrease in mesh exposure rates compared heavier weighted polypropylene. Our alternate hypothesis was that ultra-lightweight polypropylene mesh was associated with either an increase or decrease in mesh exposure rates compared to heavier weighted

polypropylene.

During bivariate analysis, we compared the means of normally distributed continuous data using separate variance or pooled variance Student's t-tests where appropriate. We compared non-normally distributed data using the Mann-Whitney U tests. Categorical data was compared using Pearson's Chi-square tests. During multivariate analysis, logistic regression was used to assess independent risk factors. We entered all potential independent predictors of mesh exposure with $p<0.1$ identified during bivariate analysis. In block 1 of the logistic regression equation we entered all potential independent predictors of mesh exposure identified during bivariate analysis except for mesh type. In block 2 of the logistic regression equation, we entered mesh type to determine if it independently predicted mesh exposure after controlling for all known predictors identified during bivariate analysis. Odds ratios with 95% confidence interval (CI) estimates for mesh exposure risk were calculated for all 2 by 2 comparisons during bivariate and multivariate analysis. Significance was determined by $p<0.05$ and 95% confidence intervals that excluded 1.0 for risk estimates. Missing data were not imputed which explains why study population counts differ depending on the analysis. Statistical analysis was performed with Statistical Package for Social Sciences software (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp.).

Results:

There were 133 cases of mesh exposure identified that were matched to 261 control subjects out of the 1247 sacrocolpopexies performed between 2003 and 2013. Figure 1 is the breakdown of

mesh exposure by year. Mesh exposures alone were identified in 45.2% of cases compared to suture exposures and combined mesh and suture exposures identified in 18.5% and 36.3% of cases respectively. The cases and controls were similar with respect to age at time of surgery, BMI, estrogen status, preoperative comorbidities as measured by the Charlson Comorbidity Index, number of additional surgeries at time of sacrocolpopexy and concomitant hysterectomy. Type of concomitant hysterectomy was not associated with mesh erosion although we did notice a higher number of supracervical hysterectomies in our control group (5) compared to our cases (1) suggestive of a protective effect for mesh exposure if an increasing number of supracervical hysterectomies were performed. Cases differed from controls in several areas including smoking, prior sacrocolpopexy preoperative leading edge of prolapse, ICS stage IV prolapse, duration of surgery, immediate and delayed perioperative complications as measured by Clavien-Dindo scores and the Comprehensive Complication Index respectively as well as mesh and suture types (Table 3).

Consistent with prior studies, current smokers were at an increased rate of mesh exposure compared to past or nonsmokers (50% vs 23.9% vs 34.4%, p=0.015). Study subjects with prior sacrocolpopexy were less likely to develop mesh exposure during the study period (p=0.03, OR 0.14, 95% CI 0.02, 1.1). The average preoperative leading edge was more advanced in mesh exposure cases compared to controls (3.1 ± 2.6cm vs 2.6 ± 2.1cm, p<0.03). Stage IV prolapse, regardless if predominately anterior (OR 3.52, 95% CI 1.61, 7.68), posterior (OR 3.07, 95% CI 1.38, 6.82) or uterine/cuff (OR 2.92, 95% CI 1.26, 6.76), was a significant risk factor for mesh exposure. ICS prolapse stages II and III were not risk factors for mesh exposure. The duration of surgery also contributed to an increased risk of mesh exposure with the average duration of

operation in cases lasting 423.5 ± 106.7 minutes compared to 400.1 ± 70.6 minutes in controls (p=0.045). This was irrespective of number of additional procedures at time of sacrocolpopexy as the number of additional procedures in mesh exposure cases was 4.5 ±1.2 compared to 4.6 ± 1.4 (p=0.624). Duration of follow up was longer in cases of mesh exposure compared to controls (38.6 ± 33.44 months vs 15.82 ± 16.58 months, p<0.001) despite collection of datum from the same study period. Immediate and delayed perioperative complications were both associated with increased risk of mesh exposure. There was a linear association between increasing Clavien-Dindo score and mesh exposure risk. Study subjects with Clavien-Dindo score of ≥3 had mesh exposure rates of 100% compared to subjects with lower scores (score 0, 28.8%; score 1, 54.2%; score 2, 64.7%). The CCI scores were similarly higher in cases than controls (2.62 ± 8.11 vs 0.31 ± 2.29, p<0.001).

Bivariate analysis of mesh and suture type is summarized in Table 5. Porcine acellular cross linked collagen matrix (Pelvicol®, CR Bard, Murray Hill, NJ) with medium weight polypropylene mesh (OR 3.15, 95% CI 1.99, 4.98) and other polypropylene mesh types (OR 2.80, 95% CI 1.29, 6.12) were associated with increased mesh exposure whereas ultra-lightweight mesh was associated with decreased mesh exposure (OR 0.17, 95% CI 0.08, 0.337). Use of polydioxanone suture (PDS II, Ethicon US, Somerville, NJ) across all areas of use including vaginal cuff (OR 0.18, 95% CI 0.06, 0.52), vaginal mesh attachment (OR 0.27, 95% CI 0.18, 0.43) and sacral attachment (OR 0.22, 95% CI 0.10, 0.50) decreased rates of mesh exposure. Conversely, use of polyester suture for vaginal mesh attachment (OR 2.35, 95% CI 1.52, 3.61) and sacral attachment (OR 2.18, 95% CI 1.37, 3.47) increased rates of mesh exposure.

Multivariate logistic regression identified six factors that independently increased the risk for mesh exposure (Table 4). Multivariate logistic regression revealed that prior surgery for incontinence (OR 2.87, 95% CI 1.19, 6.96), Porcine acellular cross linked collagen matrix with medium weight polypropylene mesh (OR 4.95, 95% CI 1.70, 14.42), other polypropylene mesh (OR 6.73, 95% CI 1.12, 40.63), Ethibond® suture for vaginal mesh attachment (OR 4.52, 95% CI 1.53, 15.37) and immediate perioperative complications measured by the Clavien-Dindo score (OR 3.64, 95% CI 1.53, 13.37) remained independent risk factors for mesh exposure. Duration of follow up minimally increased the risk of mesh exposure (OR 1.04, 95% CI 1.03, 1.06). After multivariate analysis, ultra-lightweight mesh was no longer associated with decreased rates of mesh exposure after controlling for known risk factors identified during bivariate analysis (p=0.423).

Discussion:

Prior research has identified numerous preoperative and intraoperative risk factors for mesh exposure including smoking, estrogen status, stage of prolapse, concomitant hysterectomy, number of additional procedures at time of sacrocolpopexy, mesh and suture type. Ultra-lightweight and partially absorbable lightweight polypropylene mesh has been introduced to market with the goal of reducing adverse events associated with synthetic graft implantation. Knowledge of the risk for mesh exposure when these newer synthetic materials are implanted in vivo would provide surgical guidance toward improving the outcomes in women with POP while minimizing adverse events. In our study we found that use of medium and other heavier weighted polypropylene meshes were associated with an increased risk of mesh exposure. Ultra-

lightweight polypropylene mesh was not associated with mesh exposure after controlling for other identified risk factors during bivariate analysis. Use of polyester suture for vaginal mesh attachment also increased the risk of mesh exposure independently.

Smoking and the effects of nicotine on wound healing is well studied in the literature. Lowman et al specifically looked at smoking in relation to mesh exposure in abdominal sacrocolpopexy and found that smokers had higher rates of mesh exposure (25.9% versus 7.4%, p=0.01).[13] This is consistent with our results that confirmed higher rates of mesh exposure in smokers during bivariate analysis. Preoperative discussions regarding smoking cessation should continue to be an important part of surgical counseling to decrease individual risks for mesh exposure.

A literature review revealed a paucity of studies that looked specifically at estrogen status as an independent risk factor for mesh exposure, but estrogen has been analyzed as a risk factor in studies looking at other primary risk factors such as concomitant hysterectomy, mesh type, suture type, etc.[12,22] In our study, estrogen status was not a risk factor for mesh exposure. Heterogeneity with regards to documentation of estrogen type, indication for use (vasomotor symptoms versus vaginal atrophy), route of delivery (systemic versus vaginal), preoperative or postoperative use and duration of use makes evaluation of estrogen status within and between studies difficult. Based on conflicting data, there is a need for well-designed studies looking at the effects of estrogen on mesh exposure to help clarify this risk factor. A recent randomized trial by Sun et al showed that preoperative use of vaginal estrogen twice weekly for 4-6 weeks was non-inferior to nonuse for risk of mesh exposure at one year after transvaginal mesh placement[23].

Similar to Akyol et al[19], our study revealed that advanced prolapse stage is a risk factor for mesh exposure. Our study indicated that only ICS stage IV prolapse was a significant predictor of mesh exposure whereas Akyol et al showed that stage III and greater was predictive as well. It is postulated that advancing stage of prolapse is associated with thinning of the vaginal mucosa thus providing less robust tissue available for vaginal mesh attachment leading to higher rates of mesh exposure. Conversely, vaginal wall thickening and scarring associated with previous sacrocolpopexy may explain why this factor was associated with a decreased risk of mesh exposure during bivariate analysis. Physicians can use this information to counsel patients about their risks and possible potential benefit of surgical intervention at an earlier stage.

Furthermore, Akyol et al reported that three or more additional procedures at time of sacrocolpopexy conferred greater risk of mesh exposure[19]. Our study did not reveal a difference in mesh exposure rates with the addition of multiple procedures at time of sacrocolpopexy; however, duration of procedure was a significant predictor of mesh exposure during bivariate analysis. Many factors impact duration of procedure including instruction of learners and additional procedures at time of sacrocolpopexy. Additionally, it is possible that longer procedure times are a proxy for surgical complexity such as scar or mesh revision, adhesiolysis, and/or greater blood loss that may be an unmeasured, independent risk factor. While the number of additional surgeries during sacrocolpopexy was not a risk factor for mesh exposure, study subjects with a prior incontinence surgery remained at increased risk for mesh exposure after multivariate regression analysis. A chronic inflammatory response at the surgical site related to suture or mesh used for continence may cause activation of acute phase reactants at the proximal

vagina promoting mesh exposure after sacrocolpopexy. This hypothesis warrants further investigation.

Lastly, it appears that immediate postoperative complications are an important predictor of mesh exposure. While no surgeon wants intraoperative or postoperative complications, knowing that immediate complication increases the risk for mesh exposure can help providers counsel patients postoperatively and monitor at risk patients more closely.

Mesh type used in sacrocolpopexy has and continues to evolve as studies report comparative biomechanical properties and mesh exposure data. Mesh weights, pore size and softness have been modified in hopes of reducing mesh exposure, contractile pain, dyspareunia, and infection rates. Prolene® Soft was introduced after 2000 and was the medium weight mesh type used following heavier weight polypropylene meshes in the beginning of the study period. Ultrapro® was introduced to market in 2004 and was not utilized by our practice in large numbers. Restorelle® came to market late 2010 and there has been significant utilization of the newest generation of ultra-lightweight mesh for sacrocolpopexy making possible the analysis of long-term complications such as mesh exposure. Our study is one of the first to look at mesh exposure rates for ultra-lightweight polypropylene mesh. Our study revealed that ultra-lightweight polypropylene mesh decreased the risk of mesh exposure during bivariate analysis but ultra-lightweight polypropylene mesh neither increased nor decreased the risk of mesh exposure after controlling for other identified risk factors. Because mesh exposure can take years to develop, ultra-lightweight polypropylene mesh may remain unassociated with mesh exposure or may become an independent risk factor with the passage of time. Reexamination of

mesh exposure rates using ultra-lightweight polypropylene mesh for sacrocolpopexy at a later time may yield different conclusions. However, at this time it appears that ultra-lightweight polypropylene mesh neither increases or decreases mesh exposure compared to heavier weighted polypropylene meshes which are the strongest risk factors for mesh exposure found in our study.

As previously stated, suture selection appears to be an important factor for reducing mesh exposure complications. Our study looked at suture selection for vaginal cuff closure, vaginal mesh attachment and sacral attachment. Suture selection from all sites were collected as inflammation, graph rejection, suture rejection and poor wound healing at any of the suture placement sites has the potential to impact other sites through direct extension. In a study by Shepard et al that examined suture selection and exposure rates, they found that polydioxanone suture had lower rates of mesh exposure than polyester (6/161, 3.7% versus 0/254, 0%, p=0.002) without increasing sacrocolpopexy failure[22]. The results of our study confirm that polydioxanone suture is associated with decreased rates of exposure while polyester was independently associated with increased risk of exposure during multivariate analysis. This may be due to the braided nature of polyester suture that is a potential nidus for infection leading to poor healing and subsequent mesh exposure. A similar trend was seen with the use of expanded polytrafluroethylene sutures for vaginal mesh attachment because it behaves similar to a braided, nonabsorbable suture although sample size considerations limit the validity of this conclusion. We are unable to comment on the value of nonabsorbable monofilament suture based on low utilization rates. Our study confirms that use of delayed absorbable monofilament suture is a better choice for vaginal mesh attachment during sacrocolpopexy in regards to mesh exposure.

Our research provides no evidence that use of ultra-light weight meshes and PDS suture provide

equivalent success rates compared to heavier meshes using permanent multifilament suture. However, the association of these materials with high rates of mesh exposure discourages our continued usage due to these risks.

Limitations of this study are its retrospective and non-randomized nature. Missing data from any retrospective case control study could lead to systematic error in results reporting leading to biased interpretations from true data. Results are from the experience of a single institution and thus may lack generalizability. Surgeon experience could confound the relationship between mesh type and exposure; however, surgical technique has remained constant over 25 years of surgeon experience. Utilization of CPT codes to generate the case list may underestimate the true rate of mesh exposure as CPT codes only capture surgical procedures for mesh and suture excision and fail to capture office removal and patients treated with vaginal estrogen. However, exposures identified during chart review of the control group were added to the case list. There are advantages and disadvantages to using CPT rather than ICD10 codes to categorize cases and controls. The disadvantage of using CPT codes is that we can only draw conclusions based on mesh exposure requiring surgical intervention rather than total mesh exposures treated by nonsurgical and surgical interventions. The advantage is that use of CPT rather than ICD10 provides a definitive non-debatable primary endpoint of interest to draw responsible conclusions from when identifying risk factors that may alter surgical practice. Loss of patient follow up is another limitation that may underestimate the true incidence of mesh exposure. Additionally, it is difficult to determine the directionality of the relationship between length of follow up and mesh exposure status due to the retrospective nature of our case-control study. The possibility exists that both longer follow up leads to increased mesh exposure detection rates or that mesh

exposure detection rates results in longer follow up of this complication. Strengths of this study include a large sample size.

In conclusion, ultra-lightweight polypropylene mesh neither increases or decreases mesh exposure after multivariate regression analysis compared to heavier polypropylene meshes. Additionally, polyester suture is not recommended for vaginal mesh attachment given the growing body of literature supporting monofilament use without the risk of sacrocolpopexy failure.

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Figure 1. Mesh exposure rates by year

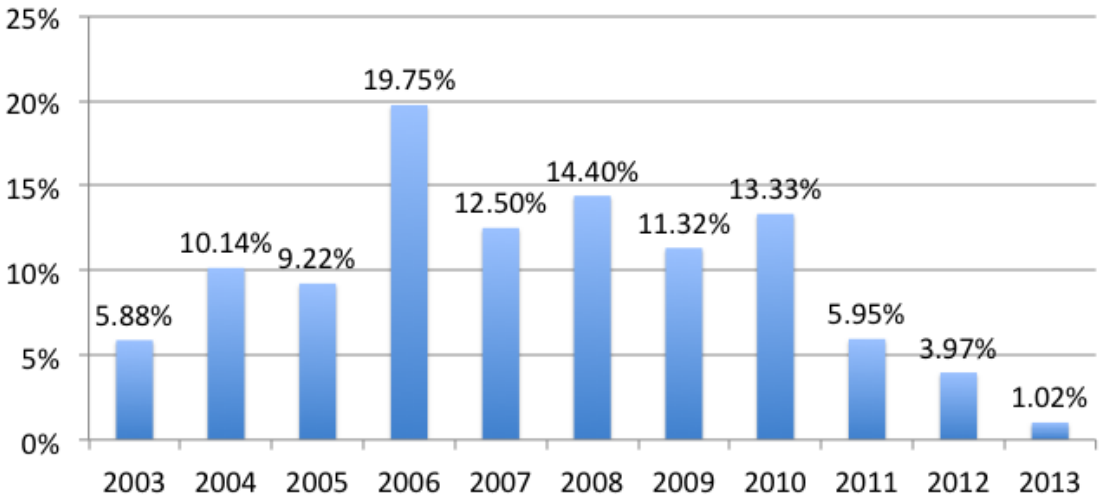

Table 1
Bivariate analysis of patient demographics and surgical characteristics for mesh exposure (N=394)

Variable	Mesh exposure (n=133)	No exposure (n=261)	P value	OR	95% CI
Age	58.7 ± 10.7	59.8 ± 9.2	0.311[a]		
BMI	27.3 ± 4.7	27.4 ± 5.6	0.884[a]		
Estrogen status			0.798[b]		
Premenopausal	22 (36.1 %)	39 (63.9%)			
Postmenopausal	90 (33.0%)	183 (67.0%)			
Postmenopausal + vaginal estrogen	21 (36.8%)	36 (63.2%)			
Smoking status			0.015[b]**		
Never	90 (34.4%)	172 (65.6%)			
Past	17 (23.9%)	54 (76.1%)			
Current	23 (50.0%)	23 (50.0%)			
Charlson Comorbidity Index	1.9 ±1.5	2.2 ±1.5	0.056[a]		
Prior Procedure for Incontinence	34 (43.0%)	45 (57.0%)	0.058[b]*	1.6	0.98, 2.70
Prior Procedure for Prolapse	37 (34.6%)	70 (65.4%)	0.885[b]		
Anterior colporrhaphy	18 (39.1%)	28 (60.9%)	0.436[b]		
Posterior colporrhaphy	17 (41.5%)	24 (58.5%)	0.287[b]		
Enterocele repair	4 (66.7%)	2 (33.3%)	0.089[b]*	3.97	0.12, 21.96
Paravaginal repair	3 (37.5%)	5 (62.5%)	0.834[b]		
Anterior vaginal mesh	3 (30.0%)	7 (70.0%)	0.786[b]		
Posterior vaginal mesh	2 (28.6%)	5 (71.4%)	0.759[b]		
Uterosacral suspension	1 (16.7%)	5 (83.3%)	0.366[b]		
Sacrospinous ligament suspension	1 (25.0%)	3 (75.0%)	1.000[c]		
Sacrocolpopexy	1 (7.1%)	13 (92.9%)	0.031[b]**	0.14	0.02, 1.1
Other	13 (39.4%)	20 (60.6%)	0.496[b]		
Preoperative leading edge	3.1 ± 2.6	2.6 ± 2.1	0.030[a]**		
Preoperative POP-Q stage					
Stage II**,** anterior	36 (29.0%)	88 (71.0%)	0.156[b]		
Stage II, posterior	32 (35.2%)	59 (64.8%)	0.792[b]		
Stage II, cuff	21 (38.9%)	33 (61.1%)	0.416[b]		
Stage III, anterior	63 (32.0%)	134 (68.0%)	0.392[b]		
Stage III, posterior	37 (37.4%)	62 (62.6%)	0.414[b]		
Stage III, cuff	38 (35.8%)	68 (64.2%)	0.641[b]		
Stage IV, anterior	18 (62.1%)	11 (37.9%)	0.001[b]**	3.52	1.61,7.68
Stage IV, posterior	16 (59.3%)	11 (40.7%)	0.004[b]**	3.07	1.38, 6.82
Stage IV, cuff	14 (58.3%)	10 (41.7%)	0.009[b]**	2.92	1.26, 6.76
Number additional procedures	4.57 ± 1.38	4.50 ± 1.24	0.625[a]		
Duration of surgery (minutes)	423.5 ± 106.7	400.1 ± 70.6	0.045[a]**		
Duration of follow up (months)	38.6 ± 33.44	15.82 ± 16.58	<0.001**		
Concomitant hysterectomy	63 (34.2%)	121 (65.8%)	0.899[b]		

[a]Normally distributed continuous data summarized as mean ± SD and compared between groups using 2-sample Student's *t*-tests.
[b]Categorical data summarized as frequency (%) and compared between groups with use of Pearson's chi-square tests.
[c]Fisher's exact test
[d]Non-normally distributed continuous data summarized as mean + SD and compared using Mann-Whitney U test.
*p<0.1, variables included in multiple regression
** p< 0.05
BMI, body mass index; TVT, tension-free vaginal tape; TOT, transobturator tape; MMK, Marshall-Marchetti-Krantz; POP-Q, Pelvic Organ Prolapse—Quantification,

Table 2
Frequency of mesh exposure based on immediate (Clavien-Dindo score) and delayed (Comprehensive Complication Index) perioperative complications

Clavien-Dindo Score	Mesh exposure (n=125)	No exposure (n=252)	P value
0	95 (28.8%)	235 (71.2%)	
1	13 (54.2%)	11 (45.8%)	
2	11 (64.7%)	6 (35.3%)	
3 and 4	6 (100%)	0 (0%)	
CCI	2.62 ± 8.11	0.31 ± 2.29	<0.001

Clavien-Dindo Score, evaluation of immediate postoperative complications prior to discharge from hospital
CCI (Comprehensive Complication Index), evaluation of delayed postoperative complications in first 3 months
P value for Clavien-Dindo score <0.001

Table 3
Bivariate analysis of mesh and suture material as risk factors for mesh exposure

Material	Mesh exposure (n=133)	No exposure (n=261)	P value	OR	95% CI
Mesh type					
Restorelle®	10 (10.6%)	84 (89.4%)	<0.001**	0.17	0.08, 0.337
Ultrapro®	5 (45.5%)	6 (54.5%)	0.417		
Pelvicol® with soft PROLENE®	99 (44.4%)	124 (55.6%)	<0.001**	3.15	1.99, 4.98
Other polypropylene	16 (57.1%)	12 (42.9%)	0.007**	2.80	1.29, 6.12
Vaginal cuff suture[b]					
Vicryl	61 (39.1%)	95 (60.9%)	0.084*	1.45	0.95, 2.22
PDS	4 (9.5%)	38 (90.5%)	<0.001**	0.18	0.18, 0.43
Vaginal mesh attachment suture[b]					
Vicryl	34 (39.1%)	53 (60.9%)	0.258		
PDS	61 (23.8%)	195 (76.2%)	<0.001**	0.27	0.18, 0.43
Ethibond®	85 (43.4%)	111 (56.6%)	<0.001**	2.35	1.52, 3.61
Gore-Tex®	36 (60.0%)	54 (40.4%)	0.172		
Other	5 (31.3%)	11 (68.8%)	0.812		
Sacral attachment material[b]					
Vicryl	2 (66.7%)	1 (33.3%)	0.268[a]		
PDS	7 (11.9%)	52 (88.1%)	0.001**	0.22	0.10, 0.50
Ethibond®	100 (40.0%)	150 (60.0%)	0.001**	2.18	1.37, 3.47
Tacks	16 (34.8%)	30 (65.2%)	0.907		
Other	12 (22.6%)	41 (77.4%)	0.060*	0.53	0.26, 1.04

Categorical data summarized as frequency (%) and compared between groups with use of Pearson's chi-square tests.
[a]Fisher's exact test
[b]Category not mutually exclusive, able to select multiple suture if used more than one type
*p<0.1, variables included in multiple regression
** p< 0.05
Restorelle®, ultra-lightweight polypropylene mesh
Utrapro®, partially absorbable lightweight mesh
Pelvicol®, porcine acellular collagen matrix
Soft PROLENE®, non-absorbable soft polyprophylene mesh
Vicryl, absorbable, braided, polyglactin 910 suture
PDS, delayed absorbable, monofilament, polydioxanone suture
Ethibond®, non-absorbable, braided polyethylene terephthalate suture
Gore-Tex®, non-absorbable, monofilament polytetrafluroethylene (ePTFE) suture
Tacks, various surgical tacks

Table 4
Multivariable logistic regression model of mesh exposure risk factors with p <0.1 on bivariate analysis

Variable	ß	P value	OR (Exp B)	CI, 95%
Prior surgery for incontinence	1.056	0.019*	2.874	1.186.956
Mesh type				
Restorelle®	0.78	0.423	2.176	0.325, 14.565
Pelvicol® with soft PROLENE®	1.60	0.003*	4.951	1.7, 14.421
Other polypropylene	1.91	0.038*	6.731	1.115, 40.628
Vaginal mesh suture				
Ethibond®	1.51	0.006*	4.524	1.531, 13.37
Clavien-Dindo Score	1.29	0.003*	3.642	1.575, 8.424
Duration of follow up	0.042	<0.001*	1.04	1.03, 1.06

Chi-square (model)=117.43, df=24, p<0.001, R^2=0.48
* p< 0.05
Restorelle, ultra-lightweight polypropylene mesh
Utrapro, partially absorbable lightweight mesh
Pelvicol, porcine acellular collagen matrix
Soft PROLENE, non-absorbable soft polyprophylene mesh
Vicryl, absorbable, braided, polyglactin 910 suture
PDS, delayed absorbable, monofilament, polydioxanone suture
Ethibond, non-absorbable, braided polyethylene terephthalate suture
Gore-Tex, non-absorbable, monofilament polytetrafluroethylene (ePTFE) suture
Tacks, various surgical tacks