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Pain Scores and Exposure Rates After Polypropylene Mesh for Pelvic Organ Prolapse

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Abstract

Objectives—To characterize pain and exposure after Prolift® placement and identify risk factors.

Methods—A case series of women who underwent Prolift® vaginal mesh were surveyed. Pain was assessed using a Visual Analog Scale. Exposure was evaluated clinically.

Results—Of 183 eligible patients, 160 completed the survey, and 45 returned for examination. Mean preoperative pain score was 0.97 and postoperative was 1.35 (p=0.12). Pre and postoperative pain scores by compartment were: anterior (1.34 vs 1.25, mean change −0.09, p-value=0.84), posterior (1.30 vs 1.56, mean change 0.26, p-value=0.72), total (0.63 vs 1.34, mean change 0.71, p-value=0.05). Graft exposure was confirmed in 23 of 183 patients (12.6%), although as asymptomatic patients were not examined, the true exposure rate may be under-estimated. Hematoma formation is independently associated with mesh exposure, adjusted OR=18.4 (95%CI 3.4-147.4, p-value =0.01).

Conclusion—While pain scores did not increase overall, there was a trend towards increased pain score in the patients with total (anterior and posterior) Prolift®. Hematoma formation significantly associated with mesh exposure.

Introduction

Pelvic organ prolapse (POP) is a prevalent problem which affects approximately 25% of women, and 12.6% of these women will eventually undergo surgical treatment.[1, 2] Traditional anterior colporrhaphy has POP recurrence rates of 30-70%, and improved anatomical and subjective results have been shown after synthetic vaginal mesh

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placement.[3-14] Reports of pain, worsening sexual function, need for additional surgery, and other complications like mesh exposure, however, have called into question the risk-benefit ratio of transvaginal mesh placement.[15-21] In their systematic review, Diwadkar, et al, found that the highest reoperation rate for prolapse was for traditional repairs, but the highest overall reoperation rate was for mesh kits when procedures for complications were added.[22] Reevaluation of previous studies has shown that clinically relevant recurrence rates with traditional repair are low.[23]

The Food and Drug Administration (FDA) Public Health Notification and Safety Communication regarding the transvaginal placement of mesh and the subsequent response from pelvic surgeons underscore the dilemma in placing mesh or not and highlight surgeon experience as an important factor in the decision process.[24-26] Potential complications of vaginal mesh placement include mesh exposure, need for additional surgery, dyspareunia, and pain, but data regarding many of the subjective problems, such as postoperative pain, which affect patients after vaginal mesh placement are limited.[22, 27-28]

This retrospective cohort study explores exposure rates and changes in pain in patients who received Prolift® from an experienced surgeon at our institution. It further aims to identify potential risk factors, for exposure or increased pain, that could either be modified or aid in counseling.

Materials and Methods

After IRB approval was obtained, this single-surgeon retrospective cohort study included both retrospective chart reviews and prospective evaluations. Inclusion criteria were all women with Pelvic Organ Prolapse Quantification System (POP-Q) stage 2-4 prolapse who underwent placement (anterior, posterior, or total, i.e. both anterior and posterior) of Prolift® vaginal mesh from January 2007 until December 2009 by the indicated surgeon (JBG). That particular time period was selected because it was after the surgeon consolidated his practice to a single institution and prior to the adoption of Prolift+M®, a newer mesh product. This surgeon had four years of experience with Prolift® and had placed over a hundred of the grafts prior to the start of the study period. Additionally, he served as an instructor who taught other surgeons how to perform the procedure.

Prolift® (Ethicon; Somerville, NJ, USA) is a type of polypropylene transvaginal mesh graft with three different versions: anterior, posterior, and total (both anterior and posterior). Although these products have been discontinued, many patients received these grafts, therefore their complication rates are pertinent.

Patients who received vaginal mesh grafts in our institution were identified by a billing database query. Records were then reviewed to confirm type of graft placement and collect historical data. Patients meeting inclusion criteria were contacted for screening with a questionnaire asking about symptoms of mesh exposure and pain (Figure 1). Initial attempts to contact patients for screening were by telephone, and certified letters were sent to those patients who were unavailable by telephone. Patients unable to be reached by any of the

telephone numbers or address available in the hospital records system were considered lost to follow up. Patients who could not speak English were excluded from the survey.

The screening questionnaire included questions about vaginal discharge, vaginal bleeding, disruptions in intercourse (partner complaining of pain or feeling something rubbing in vagina), pain, and any evaluations by other physicians due to complications of the vaginal mesh placement. There were no patient incentives for completing the survey; however patients who had a positive screening (any yes answers) on the questionnaire were offered a complimentary office visit and physical examination for evaluation of their symptoms and to determine if they had any evidence of mesh exposure.

A standard 0-to-10 visual analog scale (VAS) pain scale score was routinely collected at preoperative visits by nurses asking patients about their pain. The same VAS scale was used in the survey questionnaire to allow for comparison (Figure 1). Preoperative pain scores were obtained from the medical record, and current postoperative pain scores were obtained prospectively during questionnaire administration.

Clinical, demographic, and operative data were collected from retrospective chart review on all included patients. Screening results and clinical evaluations for patients with a positive screen were collected prospectively. Descriptive statistics were performed along with a bivariate analysis using t-test or chi-square as appropriate to identify any potential variables associated with erosion or pain. Variables evaluated included postop hematoma, chronic steroid use, age, BMI, ethnicity, smoking, diabetes, hypertension, concurrent hysterectomy, prior hysterectomy, concurrent midurethral sling, prior midurethral sling, prolapse stage, menopause status, estrogen use, pre and postop hemoglobin, postop transfusion, postoperative infection or wound breakdown, pre and postoperative pain levels and locations, adverse events, and Charlson Comorbidity Index score. Multivariate regression analysis was performed to control for confounding.

Results

A billing database query returned 361 patients who received vaginal mesh grafts at our facility during the specified time frame. Of those, 110 were performed by other surgeons, 63 were disqualified (did not meet inclusion criteria or did not have any records in our system), and 5 records were duplicates, which left 183 patients who met inclusion criteria. Of those 183 qualified patients, 2 were deceased, 3 declined to participate in the survey, 1 did not speak English, and 17 were lost to follow up. A total of 160/183 (87.4%) women met inclusion criteria and responded to the screening survey. Of the 160 patients who responded to the survey, 62 patients had a positive screen (any yes answers) and 45 of those presented for evaluation.

The mean (standard deviation (SD)) age at time of surgery was 57.9 years (11.5). Mean BMI was 29.2 kg/m^2 (5.6). Patients were predominately Caucasian (88.9%), and most were menopausal (72.7%). Mean time from date of surgery to survey response was 1238.6 ± 252.6 days or 3.4 ± 0.7 years. Other clinical and demographic data are reported in Table 1.

Mean (SD) pain score for all participants was 0.97 (2.3) preoperatively and 1.35 (2.75) postoperatively (p=0.12). The change in pain scores for preoperative pain compared to postoperative pain by compartment of graft placement were: anterior 1.34 vs 1.25 (N=44, mean change -0.09, 95% CI -0.97 to 0.79, p-value=0.84), posterior 1.30 vs 1.56 (N=27, mean change 0.26, 95%CI -1.20 to 1.72, p-value=0.72), and total 0.63 vs 1.34 (N=89, mean change 0.71, 95%CI 0.00 to 1.42, p-value =0.05).

Sub-analysis of the total Prolift® subgroup was then performed for the purposes of hypothesis generation since the differences in pain scores approached statistical significance. For the 89 patients who underwent total Prolift®, bivariate analysis found diabetes mellitus (increase in pain score 3.6 ± 3.9 p-value<0.01), concurrent hysterectomy (increase in pain score 2.0 ± 3.4 p-value=0.04) and reporting pelvic pain before surgery (decrease in pain score 1.7 ± 4.9, p-value=0.02) to be associated with changes in pain score. When multivariate analysis was performed, diabetes mellitus (increase in pain score 3.6, standard error 1.18, p-value<0.01), concurrent hysterectomy (increase in pain score 2.0, standard error 0.65, p-value<0.01), and reporting pelvic pain before surgery (decrease in pain score 1.7, standard error 1.17, p-value=0.02) all continued to have a significant association with change in pain score.

Graft exposure was confirmed in 23 of 183 patients (12.6%, 95% CI 8.5% - 18.2%). Of these, 19 were identified in clinical follow-up (either by our office or another provider) prior to the survey (10.4% of the 183), and 4 previously unidentified exposures were found in the 45 patients who presented for evaluation. Six patients with previously clinically diagnosed exposures still had exposures when examined during study evaluation. The 4 new and 6 previously identified patients with exposure makes a total of 10 out of the 45 examined patients, an exposure rate of 22.2%. Exposure rate among patients who responded to the survey was 13.1% (21 of 160, 95% CI 8.7-19.2). Two patients with known exposure did not participate in the survey (one declined, one non-English speaker). See Figure 2 for a graphical representation of subjects with exposures.

Occurrence of graft exposure was related to hematoma and postoperative back pain with unadjusted Odds Ratio (OR)=16.3 (95%CI 2.8-96.9, p-value <0.01) and unadjusted OR=7.6 (95%CI 1.4-40.3, p-value =0.03), respectively (Table 2). After logistic regression multivariable modeling, only history of hematoma was associated with graft exposure (adjusted OR=18.4, 95%CI 3.4-147.4, p-value =0.01).

Discussion

Overall baseline and postoperative pain scores were low, measuring approximately 1 on a 0-10 VAS pain scale, and there were no significant differences in overall preoperative and postoperative pain scores. Pain also did not change postoperatively in the individual compartment groups. There was a trend, however, towards increased postoperative pain in the total Prolift® subgroup (p=0.05). Patients with total mesh placement have a higher permanent mesh load than those patients who received either anterior or posterior grafts only. It is possible that increased postoperative pain may be related to larger permanent mesh load suggesting a potential for increases in contracture and scar formation.

For the purposes of hypothesis generation, a sub-analysis within the total compartment subgroup identified diabetes mellitus and concurrent hysterectomy as potential risk factors for increased pain, while patients who reported pelvic pain before surgery tended to have less pain postoperatively. It is important to note that without a comparison group of patients with native tissue multi-compartment repairs, it is impossible to determine if the trends seen are due to the increased mesh use or the larger surgical field. Larger studies involving mesh grafts and native tissue repair controls may better evaluate the relationship between permanent mesh load and postoperative pain and explore the potential impact of diabetes mellitus, comorbid pelvic pain, and concurrent hysterectomy on these mesh outcomes.

Pelvic pain and dyspareunia are multifaceted problems which are not infrequently associated with mesh augmented vaginal repairs and can be very difficult to treat.[16-17, 21] Studies of sexual function after mesh augmented prolapse repairs have had mixed results.[18, 29-32] These complications, however, are not unique to mesh augmented repairs and have been noted after native tissue repairs as well. Recent systematic review and meta-analysis of native tissue repair showed 18% of patients with worsened dyspareunia (including 4% de novo) but overall sexual function outcomes were good with the chance of stable or improved dyspareunia being 4.8 times greater than the risk of worsened dyspareunia.[33] A Cochrane review has shown no difference in dyspareunia with anterior mesh versus native tissue anterior repair.[4]

The exposure rate in this population was at a minimum 12.6%, which is similar to rates published previously in the literature (10.3%).[34] We had an excellent survey response rate of 87.4%, and 45 patients (24.6%) were evaluated in the office. However, because not every patient with symptoms was examined, some exposures may not have been captured. While the clinical significance of asymptomatic exposures is unclear, it is also probable that some asymptomatic patients had an exposure and were missed, so the true exposure rate may be underestimated.

Hematoma formation was associated with significantly increased odds of mesh exposure. Change in hemoglobin has previously been shown to be associated with mesh exposure and perhaps this decrease in hemoglobin was related to hematoma formation.[35] Knowing risk factors for exposure is important as it may help to improve patient care with better patient selection and counseling and also increased vigilance for hemostasis in the operating room and postoperatively.

A recent retrospective cohort study by El-Khawand and colleagues addressed mesh exposure rates and risk factors in 201 patients who had undergone any type of mesh-augmented anterior repair by a single surgeon.[36] Data were obtained from chart review, a variety of different mesh brands were used, and mean follow up time was 14.3 months. They reported an overall mesh exposure rate of 8.5% and found that concomitant hysterectomy and lower BMI were associated with mesh exposure. The exposure rate of the El-Khawand study was very similar (8.5%) to the current study (10.4%) except that the current study had a greater number of patients with a single mesh product, a longer follow up period, and prospective evaluation of postoperative pain.

It is interesting to note that T-incisions at the colpotomy have been implicated as a potential risk factor for mesh exposure along with concomitant hysterectomy.[34] In our study, however, no T-incisions were used as the surgeon made separate incisions for the colpotomy and the Prolift® placement, and concurrent hysterectomy was not associated with mesh exposure.

Studies have been criticized for inconsistent or insufficient surgeon experience and limited follow up periods.[26] One advantage of this study is that we analyzed longer-term outcomes in patients of an experienced surgeon who is well-trained in mesh placement. Disadvantages of this approach are that we may have missed any "learning curve" effect on outcomes and a lack of generalizability and external validity.

To reduce selection bias, all patients treated over a three-year period were included. It is a strength of the study that the majority (87.4%) of patients responded to the survey and nearly a quarter (24.6%) were objectively evaluated in office several years after surgery. There is, however, an inherent bias in that this is a retrospective cohort, and patients were selected by the surgeon for the type and compartment of mesh placement. We elected not to utilize a no-mesh arm from a group of patients who underwent native-tissue repair due to the selection bias away from placing mesh in patients with chronic pain issues. Additionally, by relying on the billing database query to obtain our population, we would have missed any patients who were mis-coded. Further limitations include the retrospective design, which allows us to identify association but not causation. It is likely that we lacked statistical power to find significant associations and instead noted trends in the total Prolift® subgroup.

The VAS pain scale in the questionnaire was selected because it was part of the standard check-in for office visits at our hospital throughout the study period (Figure 1). Since there were no other questionnaires related to pain, dyspareunia, or other pelvic symptoms that were routinely completed by all patients preoperatively, we decided not to include other measures in the postoperative and prospective portions of the study because we would not have a preoperative comparison. Additionally, the nurses read the pain scale to the patient at office visits, so reading the same scale during the telephone interviews provided similar administration style.

Patients in this study were also seen for routine postoperative visits which included pelvic examinations. Generally these visits started at 2-6 weeks postop and continued with 6-month or yearly follow up. Since the objective of this study was to evaluate longer term changes and because not all patients followed up at the same time intervals, data was not collected on pain scores from these visits or the dates they occurred. Notes from these visits were reviewed, however, to determine whether or not the patient had a mesh exposure or other complications documented prior to the study screening questionnaire. Hematoma presence, for example, was also determined by reviewing surgical and postoperative notes for mention of hematoma.

Ideally data would have been collected systematically to document the reasons why 17 of the patients with a positive screen chose not to come in for follow up examinations, however

it was not part of the questionnaire and not all patients volunteered that information. Reasons for declining visits included having moved away, having been evaluated elsewhere, and not being very bothered by symptoms; we do not have any more descriptive data regarding subjects' reasons for declining an evaluation.

Finally, the questionnaire utilized to screen for symptoms of mesh exposure and pain is not a validated measure. Since it is not validated, it is probable that some patients with pain answered "No" to the question, "Do you currently have pain that disrupts your daily life?" either pre- or post-operatively. The result could be underestimating an increase in pain that is impacting their activity level and sexual function. The quality of the study would be improved with prospective evaluation of pain using a validated questionnaire that more adequately assesses pelvic, abdominal, and coital pain.

Conclusion

Baseline pain scores overall were low and did not significantly change postoperatively; there was no change in pain postoperatively in the anterior and posterior compartment mesh groups. There was a trend towards increased postoperative pain in the total compartment mesh group. Our results suggest associations between increased pain and increased mesh load. Additionally, they show that hematoma formation was associated with mesh exposure. This information can aid in counseling patients and in future investigations aimed at better defining a potential role for transvaginal mesh.

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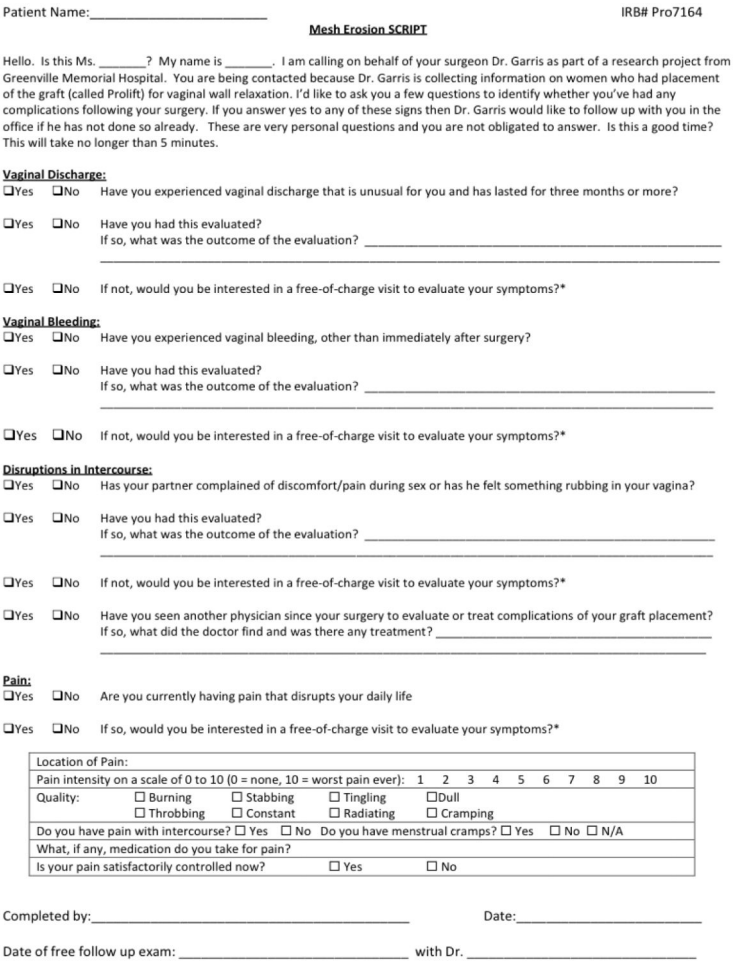

Patient Name:_____ IRB# Pro7164

Mesh Erosion SCRIPT

Hello. Is this Ms. _____? My name is _____. I am calling on behalf of your surgeon Dr. Garris as part of a research project from Greenville Memorial Hospital. You are being contacted because Dr. Garris is collecting information on women who had placement of the graft (called Prolift) for vaginal wall relaxation. I'd like to ask you a few questions to identify whether you've had any complications following your surgery. If you answer yes to any of these signs then Dr. Garris would like to follow up with you in the office if he has not done so already. These are very personal questions and you are not obligated to answer. Is this a good time? This will take no longer than 5 minutes.

Vaginal Discharge:

❑Yes ❑No Have you experienced vaginal discharge that is unusual for you and has lasted for three months or more?

❑Yes ❑No Have you had this evaluated?
If so, what was the outcome of the evaluation? _____
_____

❑Yes ❑No If not, would you be interested in a free-of-charge visit to evaluate your symptoms?*

Vaginal Bleeding:

❑Yes ❑No Have you experienced vaginal bleeding, other than immediately after surgery?

❑Yes ❑No Have you had this evaluated?
If so, what was the outcome of the evaluation? _____
_____

❑Yes ❑No If not, would you be interested in a free-of-charge visit to evaluate your symptoms?*

Disruptions in Intercourse:

❑Yes ❑No Has your partner complained of discomfort/pain during sex or has he felt something rubbing in your vagina?

❑Yes ❑No Have you had this evaluated?
If so, what was the outcome of the evaluation? _____
_____

❑Yes ❑No If not, would you be interested in a free-of-charge visit to evaluate your symptoms?*

❑Yes ❑No Have you seen another physician since your surgery to evaluate or treat complications of your graft placement?
If so, what did the doctor find and was there any treatment? _____
_____

Pain:

❑Yes ❑No Are you currently having pain that disrupts your daily life

❑Yes ❑No If so, would you be interested in a free-of-charge visit to evaluate your symptoms?*

Location of Pain:
Pain intensity on a scale of 0 to 10 (0 = none, 10 = worst pain ever): 1 2 3 4 5 6 7 8 9 10
Quality: ☐ Burning ☐ Stabbing ☐ Tingling ☐Dull ☐ Throbbing ☐ Constant ☐ Radiating ☐ Cramping
Do you have pain with intercourse? ☐ Yes ☐ No Do you have menstrual cramps? ☐ Yes ☐ No ☐ N/A
What, if any, medication do you take for pain?
Is your pain satisfactorily controlled now? ☐ Yes ☐ No

Completed by:_____ Date:_____

Date of free follow up exam: _____ with Dr. _____

Figure 1.
Interview Script for Screening Questionnaire

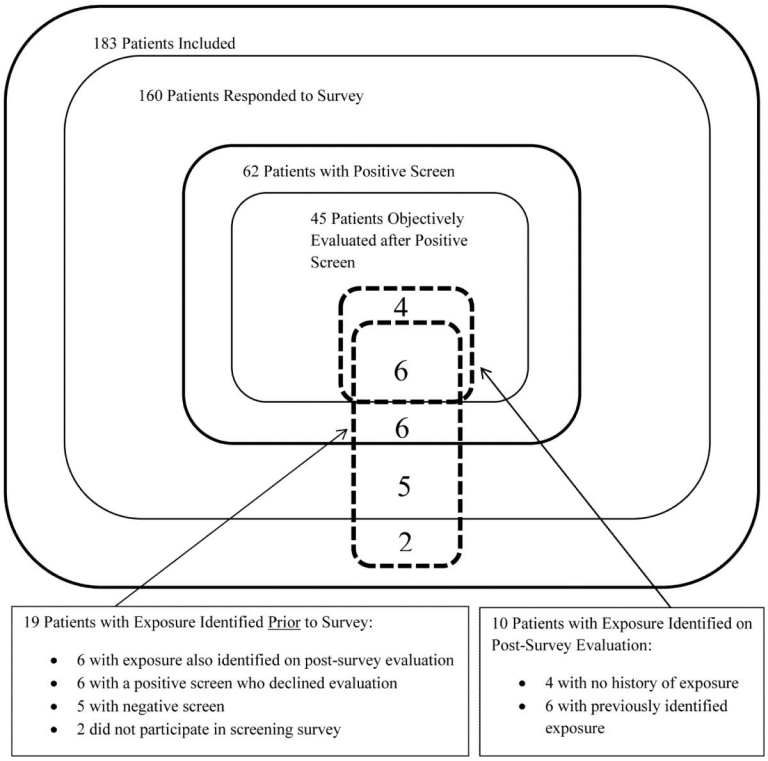

Figure 2.
Diagram of Patients Survey Completion, Positive Screening, and Exposure Identification

Table 1

Characteristics of Women Meeting Inclusion Criteria

Characteristic	N[a] = 183
Age at Time of Surgery (years), mean ± SD[b]	57.9 ± 11.5
BMI (kg/m^2), mean ± SD	29.2 ± 5.6
Race, N (%)	
Caucasian	160 (88.9)
African American	14 (7.8)
Hispanic	4 (2.2)
Other	2 (1.1)
Smokers, N (%)	15 (8.2)
CCI, mean ± SD	0.91 ± 1.1
Diabetes, N (%)	20 (10.9)
HTN, N (%)	72 (38.3)
Chronic Steroid Use, N (%)	12 (6.6)
Menopausal, N (%)	133 (72.7)
Concurrent Hysterectomy, N (%)	39 (21.3)
Previous Hysterectomy, N (%)	110 (60.1)
Preoperative POP[c] Quantification: Stage, N (%)	
II	72 (39.3)
III	99 (54.1)
IV	12 (6.6)
Preoperative Estrogen Use, N (%)	
Vaginal	19 (10.4)
Systemic	51 (27.9)
Both	1 (0.5)
Postoperative Estrogen Use, N (%)	
Vaginal	23 (12.1)
Systemic	45 (24.7)
Both	2 (1.1)
Compartment, N (%)	
Anterior	46 (25.1)
Posterior	29 (15.8)
Total	108 (59.0)
EBL (cc), mean ± SD	120.4 ± 119.3
Preoperative Pain Score (0 to 10), mean ± SD	0.97 ± 2.3

[a] N – Number

[b] SD – Standard Deviation

[c] POP – Pelvic Organ Prolapse

Table 2

Bivariate Analysis of Variables Associated with Mesh Exposure

Characteristic	Exposure
Age at Time of Surgery	0.62
BMI (kg/m^2)	0.66
Race	0.33
Smoking	0.13
Charlson Comorbidity Index	0.10
Diabetes	0.23
Hypertension	0.31
Chronic Steroid Use	0.18
Menopausal	0.19
Concurrent Hysterectomy	0.62
Previous Hysterectomy	0.15
Concurrent Midurethral Sling	0.77
Previous Midurethral Sling	0.27
Preoperative POP[a] Quantification: Stage	0.40
Preoperative Estrogen Use	0.46
Postoperative Estrogen Use	0.08
Compartment of Mesh Placement	0.53
Estimated Blood Loss (cc)	0.99
Postoperative Hematoma	<0.01
Preoperative Hemoglobin	0.23
Postoperative Hemoglobin	0.36
Postoperative Transfusion	0.76
Postoperative Infection or Wound Breakdown	0.82
Adverse Event Occurred	0.70
Preoperative Pain Score	0.20
Preoperative Pain Location	
Pelvis	0.47
Bladder	0.44
Vagina	0.19
Buttocks	0.09
Abdomen	0.67
Back	0.33
Lower Extremity	0.49
Postoperative Pain Score	0.29
Postoperative Pain Location	
Pelvis	0.63
Bladder	0.23
Vagina	0.43
Buttocks	0.87

Characteristic	Exposure
Abdomen	0.68
Back	0.03
Preoperative Dyspareunia	0.83
Postoperative Dyspareunia	0.51
Change in Pain Score (post-pre)	0.70

[a] POP – Pelvic Organ Prolapse