

What Impacts the All Cause Risk of Reoperation after Pelvic Organ Prolapse Repair? A Comparison of Mesh and Native Tissue Approaches in 110,329 Women

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Purpose: Several factors are hypothesized to impact the risks of mesh augmented pelvic organ prolapse repair, including 1) the characteristics of the material, 2) surgical experience and 3) patient selection. We present a large, population based approach to explore the impact of these factors on outcomes and describe an ideal mesh use strategy.

Materials and Methods: Data from the OSHPD (Office of Statewide Health Planning and Development) were accessed to identify all women who underwent pelvic organ prolapse repair in California from 2005 to 2011. Multivariate mixed effects logistic regression models were constructed to explore which patient, surgical and facility factors were associated with repeat surgery for a complication due to mesh or recurrent pelvic organ prolapse.

Results: A total of 110,329 women underwent pelvic organ prolapse repair during the study period and mesh was used in 16.2% of the repairs. The overall repeat surgery rate was higher in women who underwent mesh repair (5.4% vs 4.3%, $p < 0.001$). However, multivariate modeling revealed that mesh itself was not independently associated with repeat surgery. Rather, repair at a facility where there was a greater propensity to use mesh was independently associated with repeat surgery (highest vs lowest mesh use quartile OR 1.55, $p < 0.01$). Further modeling revealed that the lowest risk occurred when mesh was used in 5% of anterior and 10% of anterior apical repairs.

Conclusions: Our findings demonstrate that mesh is not independently associated with an increase in the rate of complications of pelvic organ prolapse repair on a large scale. We present a model that supports judicious use of the product on the population level which balances the risk of complications against that of recurrent pelvic organ prolapse.

Key Words: pelvic organ prolapse, surgical mesh, postoperative complications, recurrence, risk assessment

SYNTHETIC mesh was introduced in the early 2000s as a means to augment POP repair in response to data suggesting that up to 30% of POP repairs fail anatomically with time and up to 10% to 20% of women undergo subsequent surgery for recurrent

prolapse.^{1,2} After several early favorable short-term studies many practitioners adopted mesh use and by 2010 mesh products were used in approximately 13% of all prolapse repairs in the United States.³ However, with longer followup synthetic mesh for

Abbreviations and Acronyms

FDA = Food and Drug Administration

OSHPD = Office of Statewide Health Planning and Development

POP = pelvic organ prolapse

Accepted for publication February 24, 2018.

No direct or indirect commercial incentive associated with publishing this article.

The corresponding author certifies that, when applicable, a statement(s) has been included in the manuscript documenting institutional review board, ethics committee or ethical review board study approval; principles of Helsinki Declaration were followed in lieu of formal ethics committee approval; institutional animal care and use committee approval; all human subjects provided written informed consent with guarantees of confidentiality; IRB approved protocol number; animal approved project number.

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POP repair was noted to be associated with unique complications, including exposure, erosion, dyspareunia, vaginal scarring and pain.⁴ Due to the increasing number of complications reported to the MAUDE (Manufacturer and User Facility Device Experience) the FDA published an updated Public Health Notice in late 2011 with a strongly worded warning concerning the product.⁵ This resulted in a significant decrease in mesh application for vaginal POP, an increase in litigation events and the withdrawal of several products from the marketplace.

Although the FDA notice concluded that the increase in mesh related complications exceeded any benefits that it might deliver,⁵ the interpretation of mesh data remains difficult due to lack of standardization in patient selection and outcome definitions across publications.^{6–10} In addition, there is no consensus to explain why the adverse events associated with mesh use in POP repair develop. Several contributing factors are hypothesized to impact the risks associated with mesh augmented POP repair, including 1) the characteristics of the material itself, 2) the surgical experience of those performing repairs and 3) patient selection.

Like many groups we hypothesized that there would likely be some benefit to mesh when used judiciously for vaginal POP repair. Specifically this would occur when the risk of native tissue repair failure was balanced against the risks associated with mesh placement. In this study we explored on a population level the associations between specific patient/surgical factors and the need for repeat surgery after index POP repair.

METHODS

With approval from the CPHS (California Protection of Human Subjects) committee we assessed nonpublic data from the California OSHPD from 2005 to 2011. These data sets include every nonfederal surgical encounter in California and individual patients can be followed longitudinally between encounters. We chose the 2005 to 2011 period in an effort to reduce any bias that the 2011 FDA warning on mesh⁵ might have created. Information pertaining to patient demographics, past medical history and facility of care is included in addition to coding for procedures and diagnosis relevant to each encounter.

All female patients who underwent POP repair during the study period were identified (supplementary Appendix 1, <http://jurology.com/>). We defined the index case as the first POP repair in an individual during the study period. Patients were excluded from analysis if the index procedure was done for a concomitant mesh complication or for colpocleisis since obliterative procedures are considered a different category than reconstructive procedures. The compartment of repair was noted for all POP surgeries, including anterior, apical or posterior.

We identified all patients who underwent mesh augmented POP repair as well as those who underwent an incontinence procedure in addition to POP repair (supplementary Appendix 1, <http://jurology.com/>). We did not include patients in whom the index prolapse repair was performed via an abdominal approach, although this type of surgery was included when considering repeat operations.

The primary study outcome was repeat surgery, defined as any patient who underwent a subsequent surgical procedure for recurrent POP (supplementary Appendix 1, <http://jurology.com/>) or surgery for a mesh related complication. The latter was defined as any repeat surgery with a diagnosis and procedure likely attributable to a mesh complication (supplementary Appendixes 2 and 3, <http://jurology.com/>). Numerous potential diagnosis and procedure code combinations could represent repeat surgery for a mesh related complication. Therefore, each followup operation and its associated diagnoses were individually reviewed for appropriateness.

Statistical Analysis

The chi-square test for categorical variables and the Student t-test for continuous variables were used to determine univariate associations between patient, surgical and facility factors and our primary outcome (tables 1 and 2). We specifically explored the overall and mesh related repeat surgery rates between patients treated with mesh augmented and native POP repair with and without a concomitant incontinence procedure (fig. 1). We performed this analysis because an incontinence procedure (ie a suburethral sling) would likely impact the total mesh complication rate (fig. 1).

We were interested in exploring the potential impact of greater expertise on potentially superior mesh related outcomes. Thus, we grouped our cohort by facility type, including 1) academic centers, defined as centers with urology and/or obstetrics/gynecology residency programs,

Table 1. Characteristics of patients undergoing POP repair with and without mesh

	Total Cohort	Mesh	No Mesh
No. pts	110,329	17,906	92,423
Mean age*	58.2	61.5	57.5
No. payer (%):			
Private*	67,005 (60.7)	10,079 (56.3)	56,926 (61.6)
Medicare	32,238 (31.0)	6,813 (38.0)	27,425 (29.7)
Medicaid	7,080 (6.4)	687 (3.8)	6,393 (6.9)
Other	2,006 (1.8)	327 (1.8)	1,679 (1.8)
No. race (%):			
Caucasian*	70,955 (64.3)	12,417 (69.3)	58,538 (63.3)
Hispanic	17,612 (15.7)	2,475 (13.8)	15,137 (16.4)
Asian	5,231 (4.7)	652 (3.6)	4,579 (5.0)
African American	2,582 (2.3)	372 (2.1)	2,210 (2.4)
Other	13,949 (12.6)	1,990 (11.1)	11,959 (12.9)
No. surgical characteristics (%):*			
Anterior repair	76,244 (69.1)	12,021 (67.1)	64,223 (69.5)
Apical repair	48,198 (43.6)	13,787 (77.0)	34,411 (37.2)
Posterior repair	68,512 (62.1)	10,485 (58.6)	58,027 (62.8)
Apical + anterior repair	26,718 (24.2)	8,808 (49.2)	17,910 (19.4)
Incontinence procedure	54,468 (49.4)	10,481 (58.5)	43,987 (47.6)
Hysterectomy	48,990 (44.4)	5,372 (30.0)	43,618 (47.2)
No. repeat surgeries (%)*	4,893 (4.4)	962 (5.4)	3,931 (4.3)

*Test of group means or proportions in mesh vs nonmesh groups $p < 0.001$.

Table 2. Operative trends and mesh specific complication rates at types of facilities where POP repair was performed

	Academic*	High Mesh		Other Nonacademic
		Proportion†	Vol‡	
Mean No. cases (range)/median	566.8 (128–1,680)/400	160.9 (1–879)/59	820.9 (198–1,933)/705	345.9 (3–1,993)/278
No. academic centers	24	0	7	0
Total No.:				
Facilities	24	31	46	254
Anterior repairs	7,810 (57.4)	3,459 (69.3)	24,324 (64.4)	61,910 (70.5)
Apical repairs	7,952 (58.5)	2,784 (55.8)	20,595 (54.5)	36,711 (41.8)
Posterior repairs	7,909 (58.1)	3,355 (67.3)	24,001 (63.6)	54,667 (62.2)
Apical + anterior	3,687 (27.1)	1,783 (35.7)	11,414 (30.2)	20,846 (23.7)
Incontinence procedures	7,407 (54.5)	2,983 (59.8)	20,080 (52.2)	47,712 (48.6)
Repeat surgeries	596 (4.4)	283 (5.7)	2,030 (5.4)	3,891 (4.4)
No. mesh repairs (%):	2,215 (16.3)	2,417 (48.5)	10,009 (26.5)	13,274 (15.1)
Anterior	1,106 (49.9)	1,770 (73.2)	6,615 (66.1)	9,145 (68.9)
Apical	1,908	1,680 (69.5)	8,113 (81.1)	10,199 (76.8)
Anterior + apical	887 (40.0)	1,177 (48.7)	5,267 (52.6)	6,744 (50.8)
Incontinence procedures	1,214 (54.8)	1,687 (69.8)	6,075 (60.7)	7,580 (57.1)
Repeat surgeries	128 (5.8)	144 (6.0)	586 (5.9)	690 (5.2)
Repeat surgeries due to mesh complication	63 (2.8)	61 (2.5)	272 (2.7)	351 (2.6)

* Facility with obstetric/gynecology or urology residence program.

† At 90th percentile or greater of proportion of repairs with mesh (greater than 40%).

‡ At 90th percentile or greater of overall mesh volume (more than 109 mesh cases).

2) high mesh proportion centers, defined as centers in the 90th or greater percentile of proportion of repairs using mesh, corresponding to 40% or more of all POP repairs at the institution, 3) high mesh volume centers, defined as centers in the 90th percentile of overall mesh volume, corresponding to more than 109 mesh cases per year, and

4) any other facility where mesh was placed for POP repair.

The academic center group was included specifically because these facilities would be unlikely to have a distribution of cases that was less complex (tertiary referral centers) than the other groups. This served as a proxy for

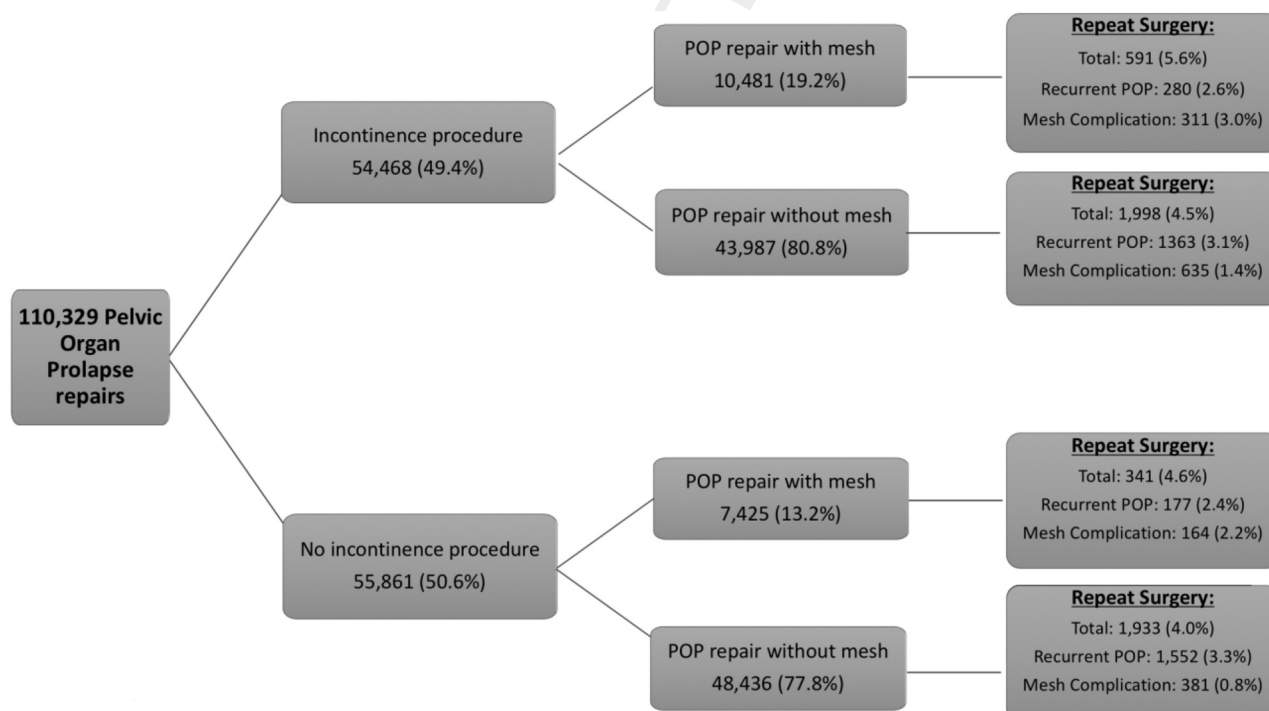


Figure 1. Independent effects of incontinence procedure and mesh use for POP repair on mesh complication repeat surgery rates. Concomitant incontinence procedure increased incidence of additional surgery for mesh complications by similar 0.7% to 0.8% rate regardless of mesh for POP repair. Similarly mesh for POP repair increased incidence of additional surgery for mesh complications by 1.5% to 1.6% regardless of incontinence procedure. We hypothesized that 0.7% repeat surgery rate for mesh complication in no mesh, no incontinence surgery group was due to likelihood that some patients underwent mesh surgery prior to study period.

case complexity. Also, since no academic center was a high mesh proportion facility, it would be difficult to argue that mesh was often used at the centers because more complex cases were treated there.

Multivariate mixed effects logistic regression models were used to explore the independent effects of variables of interest on the odds and the probability of requiring repeat surgery (table 3). The model included a measure of the propensity to place mesh at a facility, defined as the proportion of overall repairs that used mesh. We included the random effect of the facility of repair to account for any baseline variation in outcome at the facility level that was not accounted for by our fixed effects.

Because we were interested in exploring whether there was a specific mesh strategy that minimized the probability of repeat surgery, we plotted the predicted probability from our model of an individual requiring a repeat operation against the proportion of repairs using mesh at placement facilities for each POP compartment. Sensitivity analysis was performed in cases of single compartment repair alone to eliminate confounding of multicompartment repair as our data set did not allow for accurate identification of the compartment of mesh placement in cases of multicompartment repairs.

Statistical analysis was done with R, version 3.3.2 (<https://www.r-project.org/>). Two-sided $p = 0.05$ was considered statistically significant. Modeling was

Table 3. Multivariate mixed effects logistic modeling of probability of repeat operation after POP repair

Fixed Effects	OR (95% CI)	p Value
Age	0.99 (0.99–1.01)	0.73
Race:		
Caucasian	Referent	–
Hispanic	0.70 (0.64–0.77)	<0.001
African American	0.69 (0.55–0.85)	<0.001
Asian	0.53 (0.44–0.63)	<0.001
Other	0.79 (0.72–0.88)	<0.001
Payer:		
Medicare	Referent	–
Private	1.17 (1.07–1.27)	<0.001
Medicaid	1.17 (1.01–1.37)	0.04
Other	1.04 (0.82–1.33)	0.73
Comorbidity:		
Obesity	1.25 (1.06–1.46)	0.006
Diabetes mellitus	1.05 (0.96–1.16)	0.31
Coronary artery disease	1.01 (0.90–1.13)	0.89
Hypertension	1.56 (1.46–1.67)	<0.001
Academic center	0.85 (0.71–1.02)	0.09
Repair:		
Anterior	1.18 (1.10–1.26)	<0.001
Apical	1.09 (1.02–1.16)	0.01
Posterior	0.88 (0.83–0.94)	<0.001
Total facility vol	0.99 (0.99–1.00)	0.60
Incontinence procedure	1.09 (1.02–1.15)	0.006
Mesh placed	1.05 (0.96–1.13)	0.27
Mesh facility procedures (quartile):		
1 (less than 6.3%)	Referent	–
2 (6.3% or greater-less than 13.5%)	1.14 (0.99–1.33)	0.08
3 (13.5% or greater-less than 24.7%)	1.25 (1.08–1.46)	0.003
4 (greater than 27.4%)	1.55 (1.33–1.80)	<0.001

Facility was random effect and repeat operation was subsequent POP repair or surgery due to mesh problem and except for referents express odds are relative to lack of factor.

performed with the lme4 package (<https://cran.r-project.org/web/packages/lme4/index.html>).

RESULTS

Of the 110,329 identified women who underwent POP repair during the study period 17,906 (16.2%) received mesh augmentation. Mean followup in the cohort was 3.5 years (median 3.6 years) and 85% of repeat surgeries were done within 3.3 years of the index operation. The overall repeat surgery rate was higher in patients with mesh augmented repair (5.4% vs 4.3%, $p < 0.001$, table 1). However, this was tempered by the higher proportion of apical repairs (77.0% vs 37.2%, $p < 0.001$) and concomitant incontinence procedures (58.5% vs 47.6%, $p < 0.001$) in women who underwent mesh augmented repair. Interestingly although mesh augmentation decreased the risk of repeat surgery for recurrent POP by approximately 0.7%, it also resulted in an approximate 1.5% increase in repeat surgery for a mesh complication regardless of a concomitant incontinence procedure (fig. 1).

Analysis of our cohort by facility type revealed similar repeat surgery rates in patients treated with mesh augmented repair (5.2% to 6.0%, $p = 0.12$, table 2). Facilities where more mesh repairs were performed as determined by total surgical volume or proportion did not show superior mesh related outcomes. Since mesh augmentation was associated with an overall higher repeat surgery rate regardless of facility, the repeat surgery rate was driven by the proportion of repairs with mesh and not by greater relative success of mesh based repairs (table 2).

Multivariate analysis revealed that anterior repair (1.18, $p < 0.001$), apical repair (1.09, $p < 0.001$) and a concomitant incontinence procedure (1.09, $p = 0.006$) were associated with increased odds of repeat surgery while posterior repairs (0.88, $p < 0.001$) were associated with decreased odds of repeat surgery (table 3). Notably mesh augmentation was not independently associated with increased odds of repeat surgery. Rather, the propensity of mesh augmentation to be performed at a facility was significantly associated with increased odds of repeat surgery. With the lowest quartile of the proportion of mesh repairs serving as the baseline there was a progressive increase in the relative odds of a repeat surgery when moving from lower to higher quartiles (OR 1.14, 1.25 and 1.55, $p = 0.08$, 0.003 and < 0.001 , respectively).

Plots comparing the predicted risk of repeat surgery by the proportion of mesh use per compartment revealed that the minimum predicted probability of repeat surgery occurred when mesh was applied in 5% of anterior repairs and 10% of combination

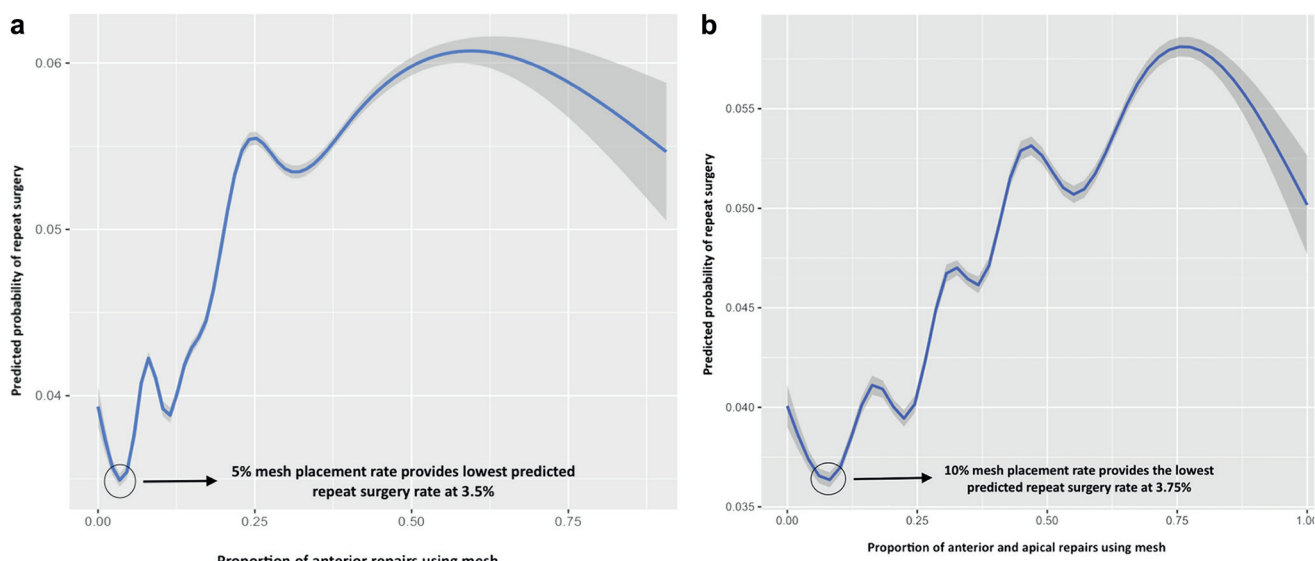


Figure 2. Best repair outcomes (blue curves) and 99% CI (gray curves). For anterior repairs approximately 5% overall mesh rate provided best outcome (a). Sensitivity analysis of anterior compartment only repairs revealed similar findings. For anterior and apical combined repairs approximately 10% mesh rate provided best outcome (b). Sensitivity analysis of anterior and apical compartment only repairs revealed similar findings.

[F2] anterior-apical repairs (fig. 2). Mesh augmentation provided no benefit for posterior repairs. These findings persisted on sensitivity analysis considering only single compartment repair.

DISCUSSION

We present a large, population based study of 110,329 women who underwent POP repair between 2005 and 2011 in California. The repeat surgery rate was higher for mesh augmentation overall. However, multivariate modeling controlling for patient and surgical factors revealed that not mesh itself but rather an increased facility propensity for mesh augmentation to be performed was what impacted the risk of repeat surgery. Although there were no superior mesh specific outcomes at facilities where there was more mesh augmentation experience, we observed that specific mesh augmentation proportions minimized the overall risk of repeat surgery whether it was related to recurrent prolapse or mesh. This provides evidence against the hypothesis that mesh itself or surgical volume alone is independently responsible for mesh based POP outcomes. Instead it provides evidence that patient selection has an important role.

Our reported complication rates are lower than in other studies with a complication rate of up to 15% due to vaginal mesh¹¹ because our complication rates were strictly defined using repeat surgery. We were unable to account for subjective outcomes (pain) or complications managed nonoperatively. As

expected, our findings are thus consistent with studies in which outcomes were defined as repeat surgery, such as an aggregated review of 12 publications demonstrating an overall 5% reoperation rate in native tissue repair groups, similar to our 4.25% rate, and a 9% rate in the mesh repair groups, higher than our 5.4% rate but showing a similar trend.¹² Another group reported the same 5.6% rate of repeat surgeries as we did for combined incontinence procedure and mesh augmented POP repairs as well as a similar rate of repeat surgery for mesh augmentation POP repair alone (4.6% vs 4.3%).¹³

It is interesting to compare our findings to those of the recently published PROSPECT (Prolapse Surgery: Pragmatic Evaluation and randomised Controlled Trials) study, a multicenter, randomly controlled trial comparing native tissue and mesh augmented POP repairs.¹⁴ In that study mesh decreased the risk of reoperation for recurrent POP by about 1% but this was superseded by a 4% specific reoperation rate for mesh complications. Given that there was no difference in subjective symptoms between the native tissue and mesh repair groups, the investigators concluded that there is no benefit to mesh augmentation. However, the key point in that study is that mesh augmentation was randomly assigned to patients without regard to the risk of native tissue failure. In most patients in the study the POP-Q (POP-Quantification) stage was 2 and fewer than 1% had a POP-Q stage of 4. In other words mesh was not placed judiciously, which is

something that we would argue against based on our findings.

Our study has limitations common to all studies using administrative data sets. We were unable to identify women who had undergone procedures prior to the start of our study timeline or outside of California during followup. Further, our results depended entirely on data set coding reliability, although OSHPD previously reported a low error tolerance level of less than 2%.¹⁵

Another important limitation is the lack of information on prolapse severity. Fortunately the impact of this on our conclusions was likely limited when considering that academic centers had the lowest overall complication rate, driven in part by specific mesh use rates, although they were more likely to have a strong representation of more complex cases. Additionally, we included the random effect of facility in our modeling to control for facility level variation in outcomes that were not specifically accounted for by our fixed effects (ie the distribution of case complexity or mesh type). This level of control also addressed another limitation of our data set, specifically that we did not have information on individual surgeons (ie the level of training).

Despite the mentioned weaknesses our study has many notable strengths. It is a large, population based study, to our knowledge the largest of its kind, which explored the risks and benefits of mesh in POP repair. This allowed us to control for factors that may impact the results of single institution studies or even large multi-institution studies with small cohorts. As our study included every surgery at nonfederal facilities in California, which is home to 14% of the entire United States population (more than 37 million persons in 2010), we were able to analyze data on a wide range of facilities, surgeons and patients. Our data set also includes all payer types, which makes the results more generalizable compared to results using single payer data sets.

Further, our study has the advantage of using the outcomes of mesh placement prior to the 2011 FDA statement release so that it may be a more accurate estimation of the reoperation risk free of

the impact of external forces such as litigation or the impact of the lay media, as was the case with the silicon breast implant controversy of the 1990s.^{16,17} Another strength of our study is our method of broad inclusion of all additional surgery related to complications. For example, while others defined mesh failure as a prolapse repair procedure code with a diagnosis of erosion,¹³ we rigorously reviewed each followup surgery that a patient underwent and individually reviewed all diagnosis and procedure code combinations to ensure appropriateness in defining that a subsequent surgical encounter was due to a mesh complication. Our study is also strengthened by the fact that our cohort had a mean followup of 1,300 days, which would capture a large proportion of eventual complications.

Finally, while many studies have a limited focus on 1 compartment or did not differentiate among compartments, we explored the differential results of mesh placement by individual compartment repair type while controlling for patient and facility effects.

CONCLUSIONS

We found that neither mesh nor surgical volume independently explained the increase in mesh based prolapse repair reoperations. Rather, it appears that on the population level cautious application of mesh in anterior and anterior-apical combination POP repairs optimizes the outcomes. We hypothesize that this occurs when the known anatomical durability of mesh is balanced against the risks of mesh specific complications. Thus, use in specific patients with careful patient selection may be warranted. Further research is also warranted to better understand which patients specifically are at higher risk for failure of native tissue repair and who might benefit the most from mesh augmentation. Our findings are especially important as trials are currently under way to assess the efficacy and safety of newer second generation mesh products. They will provide a comprehensive benchmark of first generation outcomes for comparison.

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EDITORIAL COMMENT

The saying, “hindsight is 20/20,” is an appropriate one in the setting of POP surgery. If the outcomes were known beforehand, the surgeon would be reassured that the correct procedure had been elected in the correct patient. Complications could be averted and outcomes optimized.

After a database review of more than 110,000 women treated with POP surgery the authors conclude that mesh use in itself may not be associated with reoperation for POP but it may be associated with additional surgery for mesh complications. Thus, when used judiciously and in the optimal patient, outcomes after mesh surgery may be optimized and complications may be minimized.

While the authors made a Herculean effort, the database review leaves the quintessential

question regarding the optimal patient as yet unanswered. Important information such as the degree of preoperative POP, the nature of presenting symptoms and bother, and the history of prior failed repairs, if any, are expectedly absent from such a database.

It is quite reassuring that in the right hands mesh surgery for POP can lead to a positive benefit-to-risk ratio. However, the right patient for these operations currently remains largely in our hindsight.

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REPLY BY AUTHORS

The comment is correct. While our large administrative data set strongly suggests that neither specific surgeon experience nor mesh itself appears to be the cause of adverse outcomes after mesh based vaginal POP surgery, it does not include the granular details to accurately predict who will and who will not have long-term surgical success with or without mesh. However, the growing presence of

“precision medicine,” ie tailoring medical decisions and treatments to an individual patient rather than to the population at large, is at hand. We should look no further than our oncologic colleagues who use the genomic blueprint of a tumor cell to customize chemotherapeutic regimens to catch a glimpse of the future of pelvic organ prolapse surgery.¹

Specifically our goal should be to someday meet a prospective surgical patient, assess her risk factors for future prolapse recurrence, including a genomic analysis of her vaginal connective tissue via blood sampling or simple office biopsy, and accurately predict her chance of successful vaginal reconstructive surgery based on approach and augmenting materials.^{2,3} This will only occur with the collection and analysis of multi-institutional outcome data with tissue banking.

To that aim we as a subspecialty must begin to think on a grander scale than we are accustomed to in order to develop an infrastructure that will someday rival what other medical subspecialties are beginning to achieve. Only then will female pelvic medicine be able to offer “precision medicine” and not rely on hindsight to choose whether mesh based prolapse repair is the proper surgical approach in a given patient.

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