



# Reoperation rates for pelvic organ prolapse repairs with biologic and synthetic grafts in a large population-based cohort

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## Abstract

**Introduction and hypothesis** As the long-term complications of synthetic mesh become increasingly apparent, re-evaluation of alternative graft options for pelvic organ prolapse (POP) repairs is critical. We sought to compare the long-term reoperation rates of biologic and synthetic grafts in POP repair.

**Methods** Using the California Office of Statewide Health Planning and Development database, we identified all women who underwent index inpatient POP repair with either a synthetic or biologic graft between 2005 and 2011 in the state of California. ICD-9 and CPT codes were used to identify subsequent surgeries in these patients for either recurrent POP or a graft complication.

**Results** A total of 14,192 women underwent POP repair with a biologic (14%) or synthetic graft (86%) during the study period. Women with biologic grafts had increased rates of surgery for recurrent pelvic organ prolapse (3.6% vs 2.5%,  $p = 0.01$ ), whereas women with synthetic grafts had higher rates of repeat surgery for a graft complication (3.0 vs 2.0%,  $p = 0.02$ ). There were no significant differences between the overall risk of repeat surgery between the groups (5.7% vs 5.6%,  $p = 0.79$ ). These effects persisted in multivariate modeling.

**Conclusions** We demonstrate in a large population-based cohort that biologic grafts are associated with an increased rate of repeat surgery for POP recurrence whereas synthetic mesh is associated with an increased rate of repeat surgery for a graft complication. These competing risks result in an equivalent overall any-cause repeat surgery rate between the groups. These data suggest that neither type of graft should be excluded from use and encourage a personalized risk assessment.

**Keywords** Biologic graft · Mesh · Pelvic organ prolapse · Synthetic

## Abbreviations

AS	Ambulatory surgery
CPT	Current procedure terminology
FDA	Food and Drug Administration
ICD-9	International Classification of Diseases, ninth edition
OSHPD	Office of Statewide Health Planning and Development
PD	Patient discharge
POP	Pelvic organ prolapse

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## Introduction

Pelvic organ prolapse (POP) is a health issue estimated to affect more than 25% of older women in their lifetime [1], with the lifetime risk of undergoing an operation for POP estimated at 12% [2, 3]. The incorporation of permanent synthetic grafts, commonly called mesh, into POP repairs is thought to improve durability compared with native tissue repairs alone [4–8]. Although the rates of prolapse recurrence at short-term follow-up are significantly reduced in repairs with synthetic mesh, longer term follow-up has demonstrated unique complications, including higher rates of de novo dyspareunia, pelvic pain, and mesh exposure [9, 10].

The use of synthetic grafts increased substantially from 2000 to 2010 with the advent of widespread commercialization [11, 12], then decreased dramatically in recent years following an increase in litigation events and multiple United States Food and Drug Administration (FDA) warnings [13–15], now

culminating in the ban of synthetic grafts in POP repairs by the FDA in April 2019 [16]. Given this recent FDA ban of synthetic mesh in POP repairs, there is a pressing need for alternative POP repair augmentation materials that maintain a durable repair with a decreased complication profile. One such alternative is the biologic graft, which may be used in POP repairs of all compartments, providing the theoretical advantage of improved tissue remodeling and prevention of graft exposure [17].

Interestingly, the use of biologic grafts has not seen an increase since the FDA updates [18], likely in part because of the limitations in surgical outcomes data. In fact, a recent systematic review was unable to draw definitive conclusions owing to study heterogeneity and poor-quality evidence [19]. To date, there have been few studies directly comparing the outcomes of synthetic and biologic mesh for POP and none report outcomes later than 2 years after repair. We sought to directly compare the long-term reoperation rates of POP repairs using synthetic mesh with repairs using biologic grafts in a large population-based cohort. We hypothesize that synthetic grafts might be associated with more graft complications and less POP recurrence than biologics, similar to what has been suggested by shorter-term outcomes.

## Materials and methods

With approval from the California Protection of Human Subjects committee (Institutional Review Board exempt), we accessed non-public data from the California Office of Statewide Health Planning and Development (OSHPD) from 2005 to 2011. The Office of Statewide Health Planning and Development collects and publishes healthcare data to maintain quality standards, and these data are used for peer-reviewed research [20–22]. All licensed California hospitals are required to submit reports to the OSHPD, where data are then screened for quality. Any record found to have an invalid entry or to contain incomplete or illogical data is deemed erroneous and a hospital's data must have an error rate under 2.0% to be accepted. In the OSHPD datasets, each patient has a unique identifier, which allows longitudinal follow-up between encounters. The Patient Discharge (PD) and Ambulatory Surgery (AS) datasets code for unique inpatient and ambulatory surgery visits respectively. When combined, they cover every single non-federal surgical encounter within the state of California. Each encounter includes up to 20 surgical procedure codes (the AS dataset utilizes Current Procedure Terminology [CPT], whereas the PD dataset utilizes International Classification of Diseases, ninth edition [ICD-9] procedure codes) and up to 25 associated diagnosis codes (ICD-9). Additional information available in the PD and AD datasets include demographics, past medical history, current diagnoses, and procedures/surgeries performed.

All women who underwent POP repair with a synthetic or biologic graft during the study period were identified in the PD

dataset, which uniquely differentiates between synthetic and biologic grafts when used for POP repair (ICD-9 procedure codes 70.95 and 70.94 respectively; Appendix Table 5). Biologic graft codes include both autologous grafts and xenografts. In addition to demographic information, such as age, race/ethnicity, payer type, and common comorbidities, we also identified operative characteristics, such as repair compartment, concurrent hysterectomy, and concurrent incontinence procedure. We included stratification by whether an incontinence procedure was performed or not, as we hypothesized that this might have an impact on complication rates. Following an initial inpatient POP repair, patients were assessed for future inpatient or outpatient surgery.

Our primary outcome was all-cause repeat surgery after index POP repair. All-cause repeat surgery was defined as a repeat surgery either for a complication related to a graft or for recurrent POP (defined as a repeat surgery in any compartment, regardless of the compartment of index repair). We longitudinally identified any patient who underwent a subsequent surgery for either POP repair (Appendix Table 5) or a graft complication during the study period. Graft complications were defined as any repeat surgery with both a diagnosis and procedure likely related to the previous graft implantation (Appendix Tables 6 and 7). As there are numerous potential diagnosis and procedure code combinations that could represent a repeat surgery for these complications, all combinations were individually reviewed for appropriateness. We performed univariate analysis of the demographic and surgical characteristics of women who received synthetic compared with biologic grafts. The Student's *t* test was used to compare continuous variables, whereas the Chi-squared test was used for categorical variables. Separate univariate analyses assessed the risk of subsequent surgery for a graft complication or recurrent POP.

We constructed Kaplan–Meier plots to explore the impact of graft type on time to repeat surgery (all-cause, recurrent POP, and graft complication). Multivariate analysis was performed using mixed effects logistic regression models with all-cause repeat surgery as the outcome and patient demographics and baseline surgical characteristics serving as the fixed effects. Specifically, the outcome measure was the first occurrence of a reoperation following the first prolapse surgery. The random effect was the index facility of repair, included to account for any baseline variation at a facility level not accounted for by our fixed effects. Separate models were created for all three major outcomes: all-cause repeat surgery, repeat surgery for recurrent prolapse, and repeat surgery for a graft complication. All statistical analysis was performed using R 3.5.0 software (R Core Team [2018]. R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL <https://www.R-project.org>). A two-sided *p* value of <0.05 was taken to indicate statistical significance.

## Results

During the study period, 14,192 women underwent POP repair with either a synthetic or a biologic graft. Of this cohort, 12,183 received a synthetic graft (85.8%) and 2,009 received a biologic graft (14.2%; Table 1). The median follow-up time through the 2011 study period was 745 days (interquartile range 385–1,131 days).

The demographic breakdown of women who received a synthetic graft was similar to that in those who received a biologic graft. The patients were mostly white (69.6%), with private payer insurance (53.1%) or Medicare (40.8%). All compartments of repair were well represented. Synthetic graft procedures more commonly involved an apical repair compared with biologic graft procedures (88.4% vs 61.2%,  $p < 0.01$ ). A concomitant incontinence procedure was slightly more common in the biologic group (62.6% vs 57.9%,  $p < 0.01$ ). In both groups, approximately 35% of patients underwent a concurrent hysterectomy (Table 1).

A total of 788 women underwent repeat surgery for any cause (5.6%), with no statistically significant difference between women who received a synthetic versus a biologic graft (5.6% vs 5.7%,  $p = 0.79$ ). Notably, women who received a biologic implant had a significantly increased rate of surgery for recurrent pelvic organ prolapse compared with those with synthetic mesh repairs (3.6% vs 2.5%,  $p = 0.01$ ). Conversely, women with synthetic mesh repairs had an increased rate of repeat surgery for a graft complication (3.0 vs 2.0%,  $p = 0.02$ ). These trends were similar when patients who underwent concomitant incontinence procedures were excluded (Tables 2, 3) and when stratified by the compartment of index repair (Appendix Table 8).

These trends were maintained over time, as demonstrated in Kaplan–Meier plots. Specifically, there were equivalent overall repeat surgery rates between the two graft types with the synthetic group having higher long-term rates of a subsequent surgery for a graft complication and the biologic group had higher a long-term rate of recurrent POP repair (Fig. 1). When stratified by concomitant incontinence surgery, women with both synthetic graft and concurrent incontinence surgery had the highest risk of requiring a repeat surgery for a graft complication (Fig. 2).

Our findings persisted in multivariate modeling. Specifically, synthetic grafts were associated with a lower rate of repeat surgery for recurrent POP (OR 0.70, 95% CI 0.52–0.95) and a higher rate of additional surgery due to a graft complication (OR 1.51, 95% CI 1.05–2.17), resulting in no significant difference in the overall risk of all-cause surgery. There were no notable associations between payer type and reoperation rates in the multivariate model. Compared with white women, women of Hispanic, Asian or other ethnicities had lower odds of reoperation for any indication. Younger age was associated with higher odds of repeat surgery for a graft complication in addition to an increased rate of all-cause reoperation. Hypertension was a risk factor for all-cause repeat surgery, graft complication, and POP

recurrence surgery. Obesity was associated with increased odds of repeat surgery for a graft complication (Table 4).

## Discussion

The overall all-cause long-term risk of reoperation following POP repair is equivalent in women who receive biologic versus synthetic grafts in a large population-based cohort. This is balanced by biologic grafts being associated with higher rates of reoperation for recurrent POP and synthetic grafts being associated with higher rates of reoperation for graft complications.

Our finding of these differing risks in synthetic and biologic grafts is consistent with existing literature. To date, there are three small randomized controlled trials directly comparing synthetic mesh with biologic graft for anterior POP repair, two of which demonstrate competing risk profiles similar to our study findings [23, 24]. In the third small RCT (comparing polypropylene mesh with porcine dermis), women receiving biologic grafts had a higher short-term failure rate and a higher graft extrusion rate [25]. There are fewer studies comparing synthetic and biologic grafts for posterior and apical compartment repairs. One randomized controlled trial comparing synthetic and biologic grafts with native tissue repairs for anterior or posterior POP repair demonstrated no difference in prolapse recurrence at 2 years. Notably, however, 7% of women in the synthetic graft arm had mesh complications compared with <1% in the biologic group [26]. Regarding apical compartment repair, two studies demonstrated no differences in objective or subjective outcomes or operative complications between the two groups up to 1 year postoperatively [27, 28].

We further identify concurrent incontinence procedures as an additional risk factor for a mesh complication. When stratified by concurrent incontinence surgery, the Kaplan–Meier analysis demonstrates that patients who undergo both a synthetic graft augmented POP repair and a concurrent incontinence procedure have the highest graft complication rate. This is consistent with previous data suggesting that synthetic mesh complications might be directly related to the volume of implanted mesh [29, 30], supporting the concept of a dose-dependent relationship.

The difference in cohort size between biologic and synthetic graft patients clearly demonstrates higher rates of synthetic graft use compared with biologic grafts during the study period. Aside from cohort size, the group demographics are similar and their racial distribution is consistent with the California population. Although differences in race, payer type, and comorbidity variation between the groups are statistically significant, there are likely no clinically relevant demographic differences. Similarly, when analyzing the influence of demographic factors on reoperation rates through multivariate analysis, there are no clear trends. Lower overall reoperation rates in Hispanic and Asian patients could suggest racial disparities in healthcare access; however, the

**Table 1** Demographics and surgical characteristics of the cohort

Characteristics	Total ( <i>n</i> = 14,192)	Biologic ( <i>n</i> = 2,009)	Synthetic ( <i>n</i> = 12,183)	<i>p</i> value
Mean age (years)	61.5	60.6	61.6	<0.01
Race				
White	9,867 (69.6%)	1,418 (70.6%)	8,449 (69.4%)	<0.01
Black	318 (2.2%)	32 (1.6%)	286 (2.3%)	
Hispanic	1,733 (12.2%)	328 (16.3%)	1,405 (11.5%)	
Asian	482 (3.4%)	52 (2.6%)	430 (3.5%)	
Other	1,792 (12.6%)	179 (8.9%)	1,613 (13.2%)	
Payer				
Private	7,541 (53.1%)	1,111 (55.3%)	6,430 (52.8%)	0.02
Medicare	5,788 (40.8%)	763 (38.0%)	5,025 (41.2%)	
Medicaid	575 (4.1%)	96 (4.8%)	479 (3.9%)	
Other	288 (20.0%)	39 (1.9%)	249 (2.0%)	
Comorbidity				
Coronary artery Disease	864 (6.1%)	95 (4.7%)	769 (6.3%)	<0.01
Hypertension	5,394 (38.0%)	739 (36.8%)	4,655 (38.2%)	0.22
Diabetes mellitus	1,471 (10.4%)	221 (11.0%)	1,250 (10.3%)	0.31
Obesity	314 (2.2%)	25 (1.2%)	289 (2.4%)	<0.01
Surgical characteristics				
Incontinence procedure	8,316 (58.6%)	1,257 (62.6%)	7,059 (57.9%)	<0.01
Hysterectomy	5,094 (35.9%)	681 (33.9%)	4,413 (36.2%)	0.04
Anterior compartment	9,270 (65.3%)	1,285 (64.0%)	7,985 (65.5%)	0.17
Apical compartment	12,000 (84.6%)	1,229 (61.2%)	10,771 (88.4%)	<0.01
Posterior compartment	8,922 (62.9%)	1,723 (85.8%)	7,199 (59.1%)	<0.01

absence of strong demographic trends reflects that the decision to undergo repeat surgery is multifactorial.

Our study has limitations common to all studies utilizing large administrative datasets. Specifically, our study can only provide a macroscopic comparison of synthetic and biologic grafts rather than a granular comparison of competing graft types. For example, we do not have information related to the brand of synthetic mesh or the type of biologic graft (autologous versus xenograft, type of autologous/xenograft, etc.). Similarly, we do not have access to quality of life outcomes, death data or patient location; therefore, we analytically assume that patients have not died or moved out of the state. Another important point is that we are only able to capture outcomes of repeat surgery; thus, women who suffered a prolapse recurrence or a mesh complication that was managed non-operatively are not accounted for. Additionally, we do not stratify by compartment of reoperation. This provides less granularity regarding POP recurrence, but is a less critical marker from the patient perspective.

Despite these limitations, our study has notable strengths. It is a population-based study with a large cohort (*n* = 14,192), several times larger than all other studies (*n* = 1,348 at most), and has a follow-up of up to 4 years. In addition, our dataset captures all non-federal surgeries in California, allowing us to accurately identify all repeat surgeries, even if a patient changed facilities for a subsequent operation (as long as the patient remained in the state). Further, all payer types and facilities are represented in our cohort, which represents an important improvement in generalizability over existing institutional studies. In addition, our cohort captures a population before to the 2011 FDA warning, thereby avoiding provider and patient biases that may have arisen following this warning. Finally, we rigorously defined graft complication outcomes, individually sorting through combinations of diagnosis and procedure codes that likely indicate a repeat surgery due to a graft complication (such as procedure “Other operations on urinary system” ICD-9 59.99 and diagnosis “Reaction due to implant or graft” ICD-9 99.660). Other studies

**Table 2** Repeat surgery after prolapse repair with concurrent incontinence repairs based on graft type (biologic versus synthetic)

Prolapse repair with concurrent incontinence repairs included	Total ( <i>n</i> = 14,192)	Biologic ( <i>n</i> = 2,009)	Synthetic ( <i>n</i> = 12,183)	<i>p</i> value
Overall repeat surgery	788 (5.6%)	114 (5.7%)	674 (5.5%)	0.79
Prolapse recurrence	382 (2.7%)	73 (3.6%)	309 (2.5%)	0.01
Graft complication	406 (2.9%)	41 (2.0%)	365 (3.0%)	0.02

**Table 3** Repeat surgery after prolapse repair alone based on graft type (biologic versus synthetic)

Prolapse repair alone	Total (n = 5,876)	Biologic (n = 752)	Synthetic (n = 5,124)	p value
Overall repeat surgery	300 (5.1%)	40 (5.3%)	260 (5.1%)	0.76
Prolapse recurrence	160 (2.7%)	27 (3.6%)	133 (2.6%)	0.12
Graft complication	140 (2.4%)	13 (1.7%)	127 (2.5%)	0.21

utilizing administrative datasets often define a repeat surgery (due to a mesh complication) as only mesh exposure, which likely underestimates the repeat surgery risk related to a graft complication.

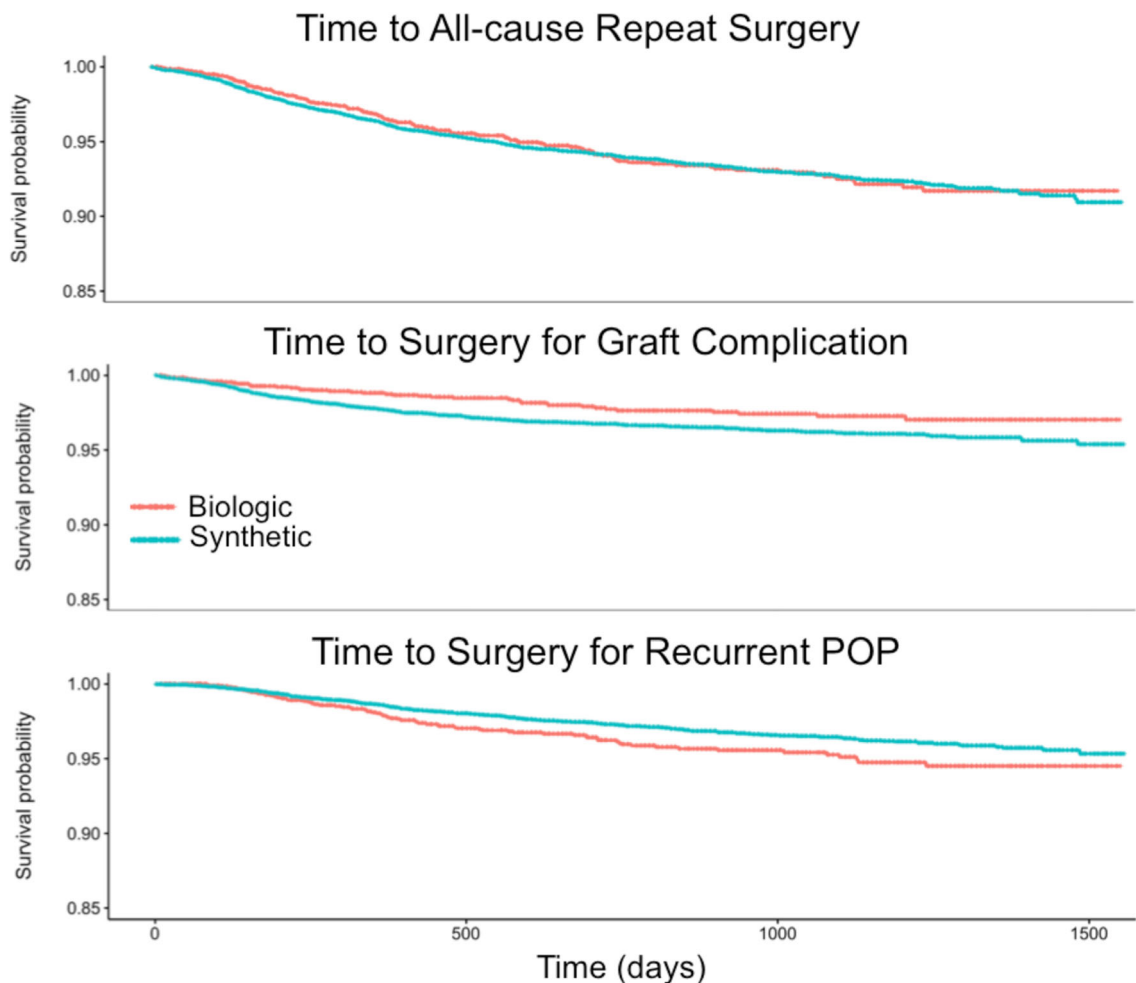
## Conclusion

Our study expands the existing literature as a large population-based study exploring the reoperation rates of biologic and synthetic mesh augmentation in POP repair. We demonstrate that biologic grafts are associated with an increased risk of repeat surgery for POP recurrence, whereas synthetic mesh is associated with an increased risk of repeat surgery for a graft complication, ultimately resulting in equivalent overall repeat surgery rates in

the two groups. These data suggest that neither type of graft should necessarily be excluded from use based on overall repeat surgery rates. However, the fact that biologic grafts provide a reduced profile of complications classically associated with synthetic mesh (i.e., exposure) makes their use appealing. We suggest that our results be used to counsel patients when discussing the long-term risks of reoperation for recurrent prolapse with biologic grafts against the risk of graft-specific complications associated with a synthetic graft. This information can further be used to design the next generation of grafts, using the individual strengths of each product.

## Compliance with ethical standards

**Conflicts of interest** None.



**Fig. 1** Time to all-cause repeat surgery, surgery for recurrent prolapse, and surgery for graft complication

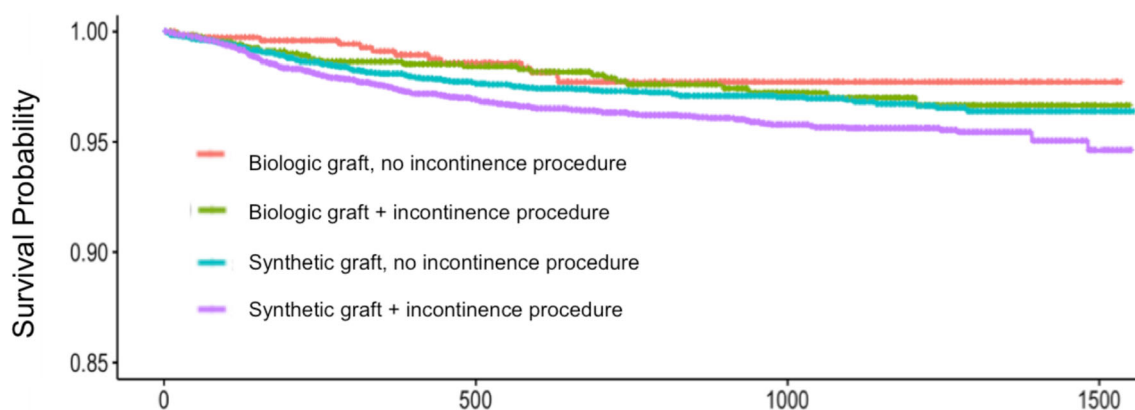


Fig. 2 Time to surgery for graft complication stratified by concurrent incontinence surgery

## Appendix

Table 4 Multivariate analysis

Characteristics	Outcome		
	All cause surgery	POP recurrence	Mesh complication
Synthetic mesh <sup>a</sup>	1.02 (0.81–1.29)	0.70 (0.52–0.95)*	1.51 (1.05–2.17)*
Index surgery <sup>b</sup>			
Hysterectomy	0.76 (0.64–0.89)*	0.80 (0.63–1.00)	0.73 (0.59–0.91)*
Incontinence procedure	1.11 (0.95–1.30)	0.96 (0.77–1.19)	1.29 (1.04–1.61)*
Anterior compartment	1.25 (1.06–1.49)*	1.10 (0.87–1.40)	1.39 (1.09–1.79)*
Apical compartment	0.85 (0.69–1.04)	0.99 (0.74–1.33)	0.75 (0.57–0.98)*
Posterior compartment	0.96 (0.81–1.13)	0.83 (0.67–1.05)	1.11 (0.88–1.39)
Age (years)	0.98 (0.98–0.99)*	1.00 (0.99–1.01)	0.97 (0.96–0.98)*
Race			
White	Reference	Reference	Reference
Black	1.02 (0.65–1.58)	0.78 (0.38–1.59)	1.20 (0.69–2.08)
Hispanic	0.55 (0.42–0.72)*	0.54 (0.37–0.80)*	0.58 (0.41–0.83)*
Asian	0.59 (0.36–0.97)*	0.49 (0.23–1.05)	0.72 (0.38–1.37)
Other	0.61(0.47–0.79)*	0.69 (0.49–1.00)*	0.56 (0.39–0.81)*
Payer			
Private	Reference	Reference	Reference
Medicare	0.91 (0.74–1.13)	1.05 (0.79–1.41)	0.75 (0.56–1.01)
Medicaid	1.32 (0.93–1.87)	1.24 (0.72–2.15)	1.27 (0.82–1.98)
Other	0.44 (0.22–0.91)*	0.41 (0.13–1.31)*	0.47 (0.19–1.18)
Comorbidity			
Coronary artery disease	1.17 (0.87–1.57)	0.94 (0.62–1.42)	1.46 (0.97–2.18)
Hypertension	1.51 (1.29–1.78)*	1.52 (1.21–1.90)*	1.47 (1.17–1.85)*
Diabetes mellitus	1.07 (0.85–1.36)	1.02 (0.73–1.43)	1.13 (0.82–1.57)
Obesity	1.22 (0.80–1.88)	0.56 (0.23–1.37)	1.77 (1.09–2.88)*

Data presented as OR (95% CI) unless otherwise specified

POP pelvic organ prolapse

\* $p < 0.05$  indicates statistical significance

<sup>a</sup> Reference is biological mesh

<sup>b</sup> Reference is absence of procedure

**Table 5** Procedure codes used to define the cohort

	Outpatient CPT <sup>a</sup>		Inpatient ICD-9	
Prolapse procedure	57120	Colpocleisis <sup>b</sup>	69.21	Uterine suspension
	57240	Repair of cystocele	69.22	Other uterine suspension
	57250	Repair of rectocele	69.23	Vaginal repair of the chronic inversion of the uterus
	57260	Repair of cystocele and rectocele	69.29	Other repair of the uterus and supporting structures
	57265	Repair of cystocele, rectocele, and enterocele	69.98	Other operation on the supporting structure of the uterus
	57268	Repair of enterocele via vaginal approach	70.50	Repair of cystocele and rectocele
	57282	Colpopexy via extraperitoneal vaginal approach	70.51	Repair of cystocele
	57283	Colpopexy via intraperitoneal vaginal approach	70.52	Repair of rectocele
	57284	Paravaginal defect repair	70.53	Repair of cystocele and rectocele with graft <sup>c</sup>
	58152	Hysterectomy and cystocele	70.54	Repair of cystocele with graft <sup>c</sup>
	58267	Hysterectomy and cystocele	70.55	Repair of rectocele with graft <sup>c</sup>
	58270	Hysterectomy with repair of enterocele	70.62	Vaginal reconstruction
	58280	Hysterectomy vaginal and partial vaginectomy with repair of enterocele	70.64	Vaginal reconstruction with mesh <sup>c</sup>
	58292	Hysterectomy vaginal (>250 g) with removal tube ± ovary and repair of enterocele	70.77	Vaginal suspension
	58293	Hysterectomy vaginal (>250 g) with colpo-urethrocystopexy	70.78	Vaginal suspension with graft <sup>c</sup>
	58294	Hysterectomy with repair of enterocele	70.80	Colpocleisis <sup>b</sup>
	58400	Uterine suspension	70.92	Other operation of the cul-de-sac (includes obliteration of cul-de-sac and enterocele repair)
	58410	Uterine suspension with presacral sympathectomy	70.93	Other operation of the cul-de-sac with graft <sup>c</sup>
			70.94	Other operation of the cul-de-sac with biologic graft
			70.95	Other operation of the cul-de-sac with synthetic mesh <sup>c</sup>
Incontinence procedure	51715	Cystoscopic injection of urethral bulking agent	57.85	Cystourethroplasty
	51840	Retropubic urethral suspension	57.89	Bladder suspension not otherwise specified
	51845	Needle suspension	59.30	Plication of the urethrovesical junction
	57288	Mid-urethral sling	59.40	Suprapubic sling operation
	57289	Pereyra procedure	59.50	Retropubic urethral suspension
			59.60	Paraurethral suspension
		59.70	Other repair for stress urinary incontinence	
Hysterectomy procedure	58150–58180	Hysterectomy	68.3–68.59	Hysterectomy
	58260–58280	Hysterectomy	68.9	Hysterectomy
				Peri-operative complication
			99.00–99.04	Blood transfusion
		998.11–998.13	Perioperative hemorrhage	

<sup>a</sup> Classified as mesh use if modifier was present (57267: insertion of mesh or other prosthesis for repair of pelvic floor defect)

<sup>b</sup> Included for recurrent POP only

<sup>c</sup> Classified as mesh use

**Table 6** Graft-related complication diagnosis codes

ICD-9	Complication diagnosis
61.90	Urinary–genital tract fistula, female
61.91	Digestive–genital tract fistula, female
61.92	Genital tract–skin fistula, female
61.98	Other specified fistulas involving female genital tract
61.99	Unspecified fistula involving female genital tract
62.32	Stricture of vagina
62.50	Dyspareunia
62.57	Vulvodynia
62.579	Other vulvodynia
62.59	Female genital organ pain
62.931	Erosion of implanted vaginal mesh and other prosthetic materials into pelvic floor muscles
62.932	Exposure of implanted vaginal mesh and other prosthetic materials into the vagina
93.90	Foreign body in bladder and urethra
93.92	Foreign body in vulva and vagina
93.99	Foreign body in unspecified site in genitourinary tract
99.630	Complication of genitourinary device or graft
99.639	Complication of genitourinary device or graft
99.659	Malfunction of graft NOS
99.660	Reaction due to implant or graft
99.665	Infectious or inflammatory reaction to genitourinary implant or graft
99.669	Infection and inflammatory reaction due to other internal prosthetic device, implant, and graft
99.670	Other complications due to unspecified device, implant, and graft
99.676	Other complications due to genitourinary device, implant, and graft
99.679	Other complications due to other internal prosthetic device, implant, and graft
596.0	Bladder neck obstruction
596.1	Intestinovesical fistula
596.2	Vesical fistula, NOS
596.9	Bladder disorder, NOS
598.1	Traumatic urethral fistula
598.2	Post-operative urethral stricture
598.8	Urethral stricture, NOS
599.1	Urethral fistula
599.4	Urethral false passage
599.6	Urinary obstruction
619.0–619.2, 619.8	Urinary–genital tract fistula, female

*NOS* not otherwise specified



**Table 7** Graft-related complication procedure codes

Outpatient		Inpatient	
CPT code	Procedure	ICD-9 code	Outpatient procedure
53040	Drainage peri-urethral abscess	480	Proctotomy
53899	Unlisted procedure urinary system	48.81	Incision of perirectal tissue
57000	Colpotomy with exploration	48.99	Other operations on rectum and perirectal tissue
57106	Partial vaginectomy	54.92	Removal of foreign body from peritoneal cavity
57130	Vaginal excision	57.84	Repair of other fistula of bladder
57135	Vaginal excision	59.99	Other operations on urinary system
57200	Vaginal cuff repair	70.12	Colpotomy
57292	Construction of vagina	70.13	Lysis of intraluminal adhesions of vagina
57295	Revision of graft to repair or remove (vaginal approach)	70.14	Other vaginotomy
57296	Revision of graft to repair or remove (abdominal approach)	70.33	Excision or destruction of lesion of vagina
57300	Closure of rectovaginal fistula	70.62	Vaginal reconstruction
57320	Closure of vesicovaginal fistula	70.64	Vaginal reconstruction with graft or prosthesis
57330	Closure of vesicovaginal fistula	70.71	Suture of laceration of vagina
57415	Removal of impacted vaginal foreign body	70.72	Repair of colovaginal fistula
57426	Revision of graft to repair or remove (laparoscopic approach)	70.73	Repair of rectovaginal fistula
58999	Removal of eroding mesh	70.75	Repair of other fistula of vagina
		70.79	Other repair of vagina
		70.91	Other operations on vagina
		70.92	Other operations on cul-de-sac
		70.93	Other operations on cul-de-sac with graft or prosthesis
		70.94	Insertion of biologic graft
		70.95	Insertion of synthetic graft or prosthesis
		71.09	Other incision of vulva and perineum
		71.71	Suture of laceration of vulva or perineum
		71.79	Other repair of vulva and perineum
		78.69	Removal of implanted devices from bone, other bones
		83.39	Excision of lesion of other soft tissue
		86.04	Other incision with drainage of skin and subcutaneous tissue
		86.05	Incision with removal of foreign body or device from skin and subcutaneous tissue
		86.22	Excisional debridement of wound, infection, or burn
		97.79	Removal of other device from genital tract
		98.17	Removal of intraluminal foreign body from vagina without incision

**Table 8** Repeat surgery stratified by prolapse compartment (including concurrent incontinence repair)

	Biologic	Synthetic	<i>p</i> value
Anterior ( <i>n</i> = 9,720)			
Overall repeat surgery	80 (6.2)	477 (6.0)	0.77
Prolapse recurrence	51 (4.0)	203 (2.5)	<0.01
Graft complication	29 (2.2)	274 (3.5)	0.03
Apical ( <i>n</i> = 12,000)			
Overall repeat surgery	60 (4.9)	582 (5.4)	0.44
Prolapse recurrence	40 (3.3)	277 (2.6)	0.16
Graft complication	20 (1.6)	305 (2.8)	0.01
Posterior ( <i>n</i> = 8,922)			
Overall repeat surgery	60 (4.9)	406 (5.6)	0.86
Prolapse recurrence	61 (3.5)	173 (2.4)	<0.01
Graft complication	20 (1.6)	233 (3.2)	0.03

All data are *n* (%) unless otherwise specified

## References

- Nygaard I, Bradley C, Brandt D. Pelvic organ prolapse in older women: prevalence and risk factors. *Obstet Gynecol.* 2004;104(3):489–97.
- Fialkow MF, Newton KM, Lentz GM, Weiss NS. Lifetime risk of surgical management for pelvic organ prolapse or urinary incontinence. *Int Urogynecol J.* 2008;19(3):437–40.
- Wu JM, Matthews CA, Conover MM, Pate V, Jonsson Funk M. Lifetime risk of stress urinary incontinence or pelvic organ prolapse surgery. *Obstet Gynecol.* 2014;123(6):1201–6.
- Sand PK, Koduri S, Lobel RW, Winkler HA, Tomezsko J, Culligan PJ, et al. Prospective randomized trial of polyglactin 910 mesh to prevent recurrence of cystoceles and rectoceles. *Am J Obstet Gynecol.* 2001;184(7):1357–62.
- Sivaslioglu A, Unlubilgin E, Dolen I. A randomized comparison of polypropylene mesh surgery with site-specific surgery in the treatment of cystocele. *Int Urogynecol J.* 2008;19(4):467–71.
- Paraiso MFR, Barber MD, Muir TW, Walters MD. Rectocele repair: a randomized trial of three surgical techniques including graft augmentation. *Am J Obstet Gynecol.* 2006;195(6):1762–71.
- Hiltunen R, Nieminen K, Takala T, Heiskanen E, Merikari M, Niemi K, et al. Low-weight polypropylene mesh for anterior vaginal wall prolapse. *Obstet Gynecol.* 2007;110(2 Pt 2):455–62.
- Nguyen JN, Burchette RJ. Outcome after anterior vaginal prolapse repair. *Obstet Gynecol.* 2008;111:891–8.
- Abed H, Rahn D, Lowenstein L, Balk EM, Clemons JL, Rogers RG, et al. Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials: a systematic review. *Int Urogynecol J.* 2011;22:789–98.
- Maher C, Feiner B, Baessler K, Christmann-Schmid C, Haya N, Marjoribanks J. Transvaginal mesh or grafts compared with native tissue repair for vaginal prolapse. *Cochrane Database Syst Rev.* 2016;2:CD012079.
- Jonsson Funk M, Edenfield A, Pate V, Visco AG, Weidner AC, Wu JM. Trends in use of surgical mesh for pelvic organ prolapse. *Am J Obstet Gynecol.* 2013;208(1):79.e1–7.
- Rogo-Gupta L, Rodriguez LV, Litwin MS, Herzog TJ, Neugut AI, Lu YS, et al. Trends in surgical mesh use for pelvic organ prolapse from 2000 to 2010. *Obstet Gynecol.* 2012;120(5):1105–15.
- Wang LC, Al Hussein Al Awamlh B, Hu JC, Laudano MA, Davison WL, Schulster ML, et al. Trends in mesh use for pelvic organ prolapse repair from the Medicare database. *Urology.* 2015;86(5):885–91.
- FDA Public Health Notifications (Medical Devices)—FDA public health notification: serious complications associated with transvaginal placement of surgical mesh in repair of pelvic organ prolapse and stress urinary incontinence. Available at <<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm061976.htm>>.
- FDA Safety Communications—update on serious complications associated with transvaginal placement of surgical mesh for pelvic organ prolapse: FDA safety communication. Available at <<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm>>.
- Food and Drug Administration. FDA takes action to protect women's health, orders manufacturers of surgical mesh intended for transvaginal repair of pelvic organ prolapse to stop selling all devices. Silver Spring: FDA; 2019. Available at: <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm636114.htm>. Accessed 28 May 2019.
- Jakus SM, Shapiro A, Hall CD. Biologic and synthetic graft use in pelvic surgery: a review. *Obstet Gynecol Surv.* 2008;63(4):253–66.
- Clemons JL, Weinstein M, Guess MK, Alperin M, Moalli P, Gregory WT, et al. Impact of the 2011 FDA transvaginal mesh safety update on AUGS members' use of synthetic mesh and biologic grafts in pelvic reconstructive surgery. *Female Pelvic Med Reconstr Surg.* 2013;19(4):191–8.
- Schimpf MO, Abed H, Sanses T, White AB, Lowenstein L, Ward RM, et al. Graft and mesh use in transvaginal prolapse repair. *Obstet Gynecol.* 2016;128(1):81–91.
- Rhoads K, Sokol E. Variation in the quality of surgical care for uterovaginal prolapse. *Med Care.* 2011;49(1):46–51.
- Raouf M, Dumitra S, Ituarte PHG, Melstrom L, Wamer SG, Fong Y, et al. Development and validation of a prognostic score for intrahepatic cholangiocarcinoma. *JAMA Surg.* 2017;152(5):e170117.
- Rajeshuni N, Johnston EE, Saynina O, Sanders LM, Chamberlain LJ. Disparities in location of death of adolescents and young adults with cancer: a longitudinal population study in California. *Cancer.* 2017;123(21):4178–84.
- Natale F, La Penna C, Padoa A, Agostini M, De Simone E, Cervigni M. A prospective, randomized, controlled study comparing Gynemesh, a synthetic mesh, and Pelvicol, a biologic graft, in the surgical treatment of recurrent cystocele. *Int Urogynecol J Pelvic Floor Dysfunct.* 2009;20(1):75–81.
- Menefee SA, Dyer KY, Lukacz ES, Simsman AJ, Lubner KM, Nguyen JN. Colporrhaphy compared with mesh or graft reinforced vaginal paravaginal repair for anterior vaginal wall prolapse: a randomized controlled trial. *Obstet Gynecol.* 2011;118:1337–44.
- Handel LN, Frenkl TL, Kim YH. Results of cystocele repair: a comparison of traditional anterior colporrhaphy, polypropylene mesh and porcine dermis. *J Urol.* 2007;178:153–6.
- Glazener CM, Breeman S, Elders A, Hemming C, Cooper KG, Freeman RM, et al. Mesh, graft, or standard repair for women having primary transvaginal anterior or posterior compartment prolapse surgery: two parallel-group, multicentre, randomised, controlled trials (PROSPECT). *Lancet.* 2017;389:381–92.
- Altman D, Anzen B, Brismar S, Lopez A, Zetterstrom J. Long-term outcome of abdominal sacrocolpopexy using

- xenograft compared with synthetic mesh. *Urology*. 2006;67:719–24.
28. Culligan P, Salamon C, Priestley J, Shariati A. Porcine dermis compared with polypropylene mesh for laparoscopic sacrocolpopexy: a randomized controlled trial. *Obstet Gynecol*. 2013;121(1):143–51.
29. Withagen MI, Vierhout ME, Hendriks JC, Kluivers KB, Milani AL. Risk factors for exposure, pain, and dyspareunia after tension-free vaginal mesh procedure. *Obstet Gynecol*. 2011;118:629–36.
30. Chughtai B, Barber MD, Mao J, Forde JC, Normand ST, Sedrakyan A. Association between the amount of vaginal mesh used with mesh erosions and repeated surgery after repairing pelvic organ prolapse and stress urinary incontinence. *JAMA Surg*. 2017;152:257–63.

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