

# Evaluation of the Effect of Surgeon's Operative Volume and Specialty on Likelihood of Revision After Mesh Midurethral Sling Placement

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**OBJECTIVE:** To estimate rates of revision surgery after insertion of mesh midurethral slings and explore whether physician specialty, annual operative volume, or hospital type are associated with this outcome.

**METHODS:** A population-based retrospective cohort of women undergoing midurethral sling procedures over a 13-year interval (2004–2017) in Alberta, Canada was created using administrative health data. The primary outcome was subsequent surgery for revision of midurethral sling, defined by a composite of surgical procedures. Exposures included annual number of midurethral sling procedures performed by the surgeon, surgeon specialty, facility type, patient age, and concomitant prolapse repair. Mixed effects logistic regression using linear spines was used to test a-priori hypothesis that annual surgical volume would be inversely related in a nonlinear fashion to risk of revision.

**RESULTS:** In the cohort of 19,511 women, cumulative rates of revision surgery were 3.84% (95% CI 3.54–4.17)

at 5 years and 5.26% (95% CI 4.82–5.74) at 10 years. The first year after midurethral sling placement was the most vulnerable window, with 0.40% (95% CI 0.31–0.49) undergoing revision within 30 days and 2.15% (95% CI 1.95–3.52) within 1 year. Concomitant prolapse repairs (odds ratio [OR] 1.24, 95% CI 1.04–1.48) and surgeon's annual volume were associated with revision. After 50 cases per year, odds of revision declined with each additional case (OR 0.99/case, 95% CI 0.98–0.99, OR 0.91/10 cases, 95% CI 0.84–0.98) and plateaued at 110 cases per year. Surgeon specialty, hospital type, and patient age were not associated with outcome.

**CONCLUSION:** One in 20 women undergo revision surgery within 10 years after midurethral sling placement. Higher physician surgical volume is associated with decreased risk, with the decline occurring at a threshold of 50 cases annually. Minimum caseload parameters for surgeons performing midurethral sling procedures may improve quality of these procedures.

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Ten years after introduction of midurethral slings for treatment of stress urinary incontinence (SUI), more than 1.2 million midurethral sling had been implanted worldwide.<sup>1</sup> Although complication rates reported in clinical trials are very low, in the range of 1–6%,<sup>2,3</sup> the release of the U.S. Food and Drug Administration's (FDA) advisory on use of pelvic mesh in 2008<sup>4</sup> and Health Canada's warning in 2010<sup>5</sup> resulted in increased attention from patients and media regarding suboptimal outcomes after these procedures. Complication rates such as the need for revision surgeries reported by clinical trials may not translate to real world practice, given that trials are generally conducted by experienced surgeons and enrollment restrictions often result in only "ideal" patients being

included. As such, trial results may be discrepant from outcomes in a heterogeneous population. Additionally, participant attrition and costs associated with trials often mean long-term follow-up for rare outcomes cannot be achieved.

Identification of risk factors for subsequent revision surgery is important, as it allows personalized preoperative counselling or avoidance of surgery in high risk cases. Previous work has suggested patient age,<sup>6</sup> concomitant prolapse surgery,<sup>7,8</sup> and surgeon's annual volume affect rates of surgical revision for midurethral sling.<sup>8</sup> Although factors such as age and concomitant prolapse may not be modifiable, addressing health systems factors such as surgeon annual clinical volume holds promise as a modifiable risk factor to improve outcomes. Prior work evaluating effect of surgeon's volume within urologic and gynecologic surgeries has dichotomized surgeon volume based on very low volumes of one or two per year,<sup>9</sup> top quartile,<sup>8</sup> or thresholds based on expert opinion.<sup>6,10</sup> Although these approaches suggest a relationship between surgical volume and outcomes, they do not fully characterize the nature of this relationship. It is not known whether a linear relationship exists, where the experience of each additional case reduces the risk of revision surgeries, or whether the relationship is more complex with occurrence of thresholds and plateaus.

Given increasing global concern about pelvic mesh, it is important to accurately determine rates of revision for midurethral sling procedures and thoroughly model the effect of surgeon experience on this outcome. This information is of timely

importance because it can be used for the development of policies and procedures aimed at improving patient outcomes after midurethral sling surgery. Using routinely collected population-based administrative data, we aimed to determine: 1) rates of subsequent surgery to revise mesh after insertion of a midurethral sling; and 2) how health system factors, including surgeon's annual surgical volume, specialty, and hospital type, affect the risk of revision.

## METHODS

Ethics approval was received from the Conjoint Health Ethics Review Board, University of Calgary (REB130760). A retrospective population-based cohort was created using de-identified administrative health data obtained from Alberta Health Services. This dataset captured all hospital visits over a 13-year interval (2004–2017) in Alberta, Canada, a province with a population of approximately 4 million. Healthcare in this setting is delivered in a universal, single-payer model and covers all individuals with Canadian citizenship, permanent resident status, or a valid work or study permit. The dataset entirely captures all members of the Alberta population eligible to receive healthcare. Waitlists in Alberta have historically been shorter than neighboring provinces, meaning it is unlikely an Alberta resident would have surgery out of province. As a result, all subsequent surgical procedures would be captured unless the woman emigrated after her midurethral sling procedure. Although estimates of annual loss due to emigration and death are not easily available within this dataset, a similar study conducted in another Canadian province showed

**Table 1. Individual Canadian Classification of Health Intervention Codes Representing Index Midurethral Sling Surgery**

CCI Code	n	Description	Years Active
1.PL.74.AL-XX-N	12,017	Fixation, bladder neck combined per orifice (vaginal) and percutaneous approach using synthetic material (eg, TVT technique)	April 2006–present
1.PL.74.CR-XX-N	5,258	Fixation, bladder neck, per orifice (vaginal) approach with incision using synthetic tissue (eg, TVT, Monarc, SPARC)	April 2009–present
1.PL.74.AL-FF	2,858	Fixation, bladder neck combined percutaneous and vaginal approach using TVT technique	April 2002–March 2006
1.PL.74.AF-XX-N	697	Fixation, bladder neck combined per orifice (vaginal) and open (abdominal) approach using synthetic material	April 2002–present
1.PL.74.LA-XX-N	562	Fixation, bladder neck open, perineal approach using synthetic material (eg, laparotomy, pubovaginal sling)	April 2006–present
1.PL.74.DA-XX-N	269	Fixation, bladder neck endoscopic (laparoscopic) approach using synthetic material (eg, laparoscopic procedure at time of TVT, laparoscopic mesh sling)	April 2009–present
1.PL.74.AF-FF	285	Fixation, bladder neck combined open, abdominal and endoscopic transvaginal approach using TVT technique	April 2002–March 2006

CCI, Canadian Classification of Health Intervention; TVT, tension free vaginal tape.

Total number exceeds 19,511 because midurethral sling cases could have more than one CCI code assigned to them.

a 1.5% emigration and 2.9% death rate in a comparable patient population over a 20-year period.<sup>8</sup>

Three databases containing person-level information on exposure, outcomes and covariates were linked by unique personal health number and gender. The component datasets are: 1) the Discharge Abstract Database, which captures all inpatient surgical procedures and subsequent hospital admissions (2004–2017), and two same-day surgery databases; the 2) the National Ambulatory Care Reporting System (2010–2017); and 3) the Ambulatory Care Classification System (2004–2009). These datasets adhere to International Classification of Diseases, Canadian Version-10<sup>11</sup> and Canadian Classification of Health Intervention<sup>12</sup> standards of coding<sup>13</sup> and have been validated as highly accurate.<sup>14–16</sup>

A study window of 2004–2017 was specifically chosen because midurethral sling procedures in Alberta began in 2002, after a formal evaluation regarding safety and economics. It is expected that, between 2002 and 2003, volumes of midurethral sling cases were low. Small numbers of surgeons performing midurethral sling procedures in the first 2 years could result in inadvertent identification. However, by 2004, midurethral sling procedures were widespread, making identification of individual surgeons unlikely. Additionally, it is expected that health information coders who submit Canadian Classification of Health Intervention codes to data sources may have required time to become accustomed to procedural codes rep-

resenting midurethral sling procedures. Finally, a transition in the framework for procedural coding was occurring between 2001 and 2006. The Canadian Classification of Diagnostic, Therapeutic and Surgical Procedures, which was comprised of 3,500 unique codes, was replaced by the Canadian Classification of Health Intervention, which provided richer data through more than 18,000 codes.<sup>17</sup> This transition was completed in Alberta by 2002,<sup>18</sup> and health information coders would have adjusted the new framework by 2004. Thus, beginning the study window in is expected to translate to accurate coding.

Surgical procedures are recorded in all three datasets using Canadian Classification of Health Intervention codes. Individuals were selected for inclusion if they were coded as undergoing a mesh-based urethral sling procedure in the study timeframe. Canadian Classification of Health Intervention coding maps midurethral sling procedures specifically to certain qualifier codes, which represent “Use of synthetic tissue, such as tension free vaginal tape [TVT], MONARC, SPARC.”<sup>19</sup> These midurethral sling procedures could be performed in isolation, or in combination with other surgical procedures. After identification of a midurethral sling procedure, first occurrence of that Canadian Classification of Health Intervention code was considered the index procedure and date. All available data on hospital readmission or day surgeries that occurred subsequent to the index midurethral sling procedure was obtained for each

**Table 2. Individual Canadian Classification of Health Intervention Codes Representing Mesh Revision Surgery**

CCI Code	n	Description	Years Active
1.PL.54.CA-XX-N	284	Management of internal device, bladder neck of synthetic urethral sling (TVT) using per orifice vaginal approach	April 2006–present
1.PL.54.LA-XX-N	37	Management of internal device, bladder neck of synthetic material (urethral sling) (TVT) using open laparotomy approach	April 2006–present
1.PL.54.LB-PZ	1	Management of internal device, bladder neck, of artificial sphincter using open approach	April 2006–present
1.PL55.CA-XX-N	311	Removal of device, bladder neck of synthetic urethral sling (TVT) using vaginal approach	April 2006–present
1.PL.55.LA-XX-N	72	Removal of device, bladder neck of synthetic urethral sling (TVT) using open laparotomy approach	April 2006–present
1.PL.55.LB-PZ	0	Removal of device, bladder neck, of artificial sphincter using open approach	April 2006–present
1.PQ.56.*	4	Removal of foreign body, any approach	April 2002–present
1.PQ.57.*	1	Extraction of material from urethra, any approach	April 2002–present
1.PQ.59.*	5	Destruction urethra, any approach	April 2002–present
1.PQ.72.*	49	Release urethra, by any approach (eg urethrolisis)	April 2002–present
1.PQ.86.*	12	Closure of fistula, urethra, by any approach	April 2002–present

CCI, Canadian Classification of Health Intervention; TVT, tension free vaginal tape.

Total number exceeds 770 because revision cases could have more than one CCI code assigned to them.

\* Indicates options in the coding rubric of the Canadian Classification of Health Interventions system. When used, it means all codes after the main stem fall into this category.

**Table 3. Descriptive Characteristics of Midurethral Sling Cases by Year of Insertion**

Year	n (%)	Age (y)	Concomitant POP Surgery (%)	MUS Cases/Surgeon	Urology vs Gynecology (%)	
Cohort	19,511 (100)	52.1±11.5	29.7	55 (20–117)		
2004	1,374 (7.04)	53.5±12.3	26.9	52 (44–63)	34.7	65.3
2005	1,688 (8.65)	52.4±11.6	26.5	51 (44–59)	36.0	64.0
2006	1,549 (7.94)	52.6±11.4	27.2	51 (45–60)	29.2	70.8
2007	1,617 (8.29)	51.7±11.3	26.0	50 (44–59)	32.9	67.1
2008	1,652 (8.47)	52.3±11.6	25.0	51 (44–60)	30.1	69.9
2009	1,661 (8.51)	51.9±11.2	24.9	50 (44–59)	29.5	70.5
2010	1,628 (8.34)	51.6±11.3	29.0	50 (44–58)	27.1	72.9
2011	1,691 (8.67)	51.7±11.3	29.2	50 (44–59)	27.0	73.0
2012	1,580 (8.10)	51.8±11.5	32.1	50 (44–59)	27.4	72.6
2013	1,399 (7.17)	51.5±11.2	34.7	50 (43–59)	24.4	75.6
2014	1,315 (6.74)	52.0±11.7	36.08	50 (43–60)	19.7	80.3
2015	1,252 (6.42)	51.8±11.7	36.2	50 (43–59)	20.9	79.1
2016	1,105 (5.66)	52.1±11.7	37.7	50 (43–60)	23.6	76.5
<i>P</i>		<.001*	<.001 <sup>†</sup>	<.001 <sup>‡</sup>		<.001 <sup>§</sup>

POP, pelvic organ prolapse; MUS, midurethral sling.

Data are mean±SD, %, or median (interquartile range) unless otherwise specified.

\* Analysis of variance.

<sup>†</sup> Chi-square.

<sup>‡</sup> Mann Whitney U.

<sup>§</sup> Kruskal-Wallis.

individual. Although Canadian Classification of Health Intervention codes can determine whether route of placement for mesh sling procedures were per orifice vaginal surgeries, laparotomy or laparoscopy, the anatomic variant of sling (retropubic vs transobturator), and device manufacturer is not identifiable.

In all patients with first occurrence of a midurethral sling procedure, outcome of a subsequent surgery for sling complications is a binary outcome defined by Canadian Classification of Health Intervention codes representing removal or revision of implanted surgical devices or mesh, removal of a urethral foreign body,

**Table 4. Rates of Revision Surgery at Various Time Intervals**

Interval of Time After Index Surgery	No. of Patients		Mesh Complications	
	At Start of Follow-up Interval	Censored Owing to Incomplete Follow-up	No. of Cases	Proportion of Individuals [% (95% CI)]
Noncumulative rates of revision surgery by timeframe				
30 d or less	19,511	116	77	0.40 (0.31–0.49)
More than 30 d–1 y	19,318	895	331	1.75 (1.57–1.95)
More than 1 y–2 y	18,092	930	125	0.71 (0.59–0.84)
More than 2 y–3 y	17,037	1,190	67	0.41 (0.32–0.52)
More than 3 y–4 y	15,780	1,339	58	0.38 (0.29–0.50)
More than 4 y–5 y	14,383	1,521	33	0.24 (0.17–0.34)
More than 5 y–6 y	12,829	1,650	34	0.28 (0.19–0.40)
More than 6 y–7 y	11,145	1,598	28	0.27 (0.18–0.39)
More than 7 y–8 y	9,519	1,627	33	0.38 (0.26–0.53)
More than 8 y–9 y	7,859	1,613	14	0.20 (0.11–0.33)
More than 9 y–10 y	6,232	1,608	19	0.35 (0.21–0.55)
Cumulative rates of revision surgery by timeframe				
Within 1st y of surgery	19,511	1,072	408	2.15 (1.95–2.37)
3 y postsurgery	18,431	2,588	600	3.24 (2.98–3.52)
5 y postsurgery	15,974	2,854	691	3.84 (3.54–4.17)
10 y postsurgery	13,120	7,892	819	5.26 (4.82–5.74)

**Table 5. Multi-Variable Mixed-Effects Logistic Regression Model Evaluating the Relationship of Patient and Health System Factors to the Outcome of Revision Surgery After Midurethral Sling Placement**

Variable	Adjusted OR	95% CI	P
Patient age (y)	1.00	0.99–1.01	.974
Duration of follow-up (y)	1.02	1.00–1.05	.054
Concomitant native tissue prolapse surgery	1.24	1.04–1.48	.018
Academic hospital (reference)			
Urban hospital	0.81	0.62–1.04	.108
Rural hospital	0.81	0.58–1.12	.196
Urologist (reference)			
Gynecologist	0.95	0.69–1.30	.737
Annual volume of MUS inserted			
1–50 cases, per additional 10 cases	1.01	0.94–1.10	.914
51–110, per additional 10 cases	0.91	0.84–0.98	.024
110 or more cases, per additional 10 cases	1.01	0.95–1.08	.794

OR, odds ratio; MUS, midurethral sling.

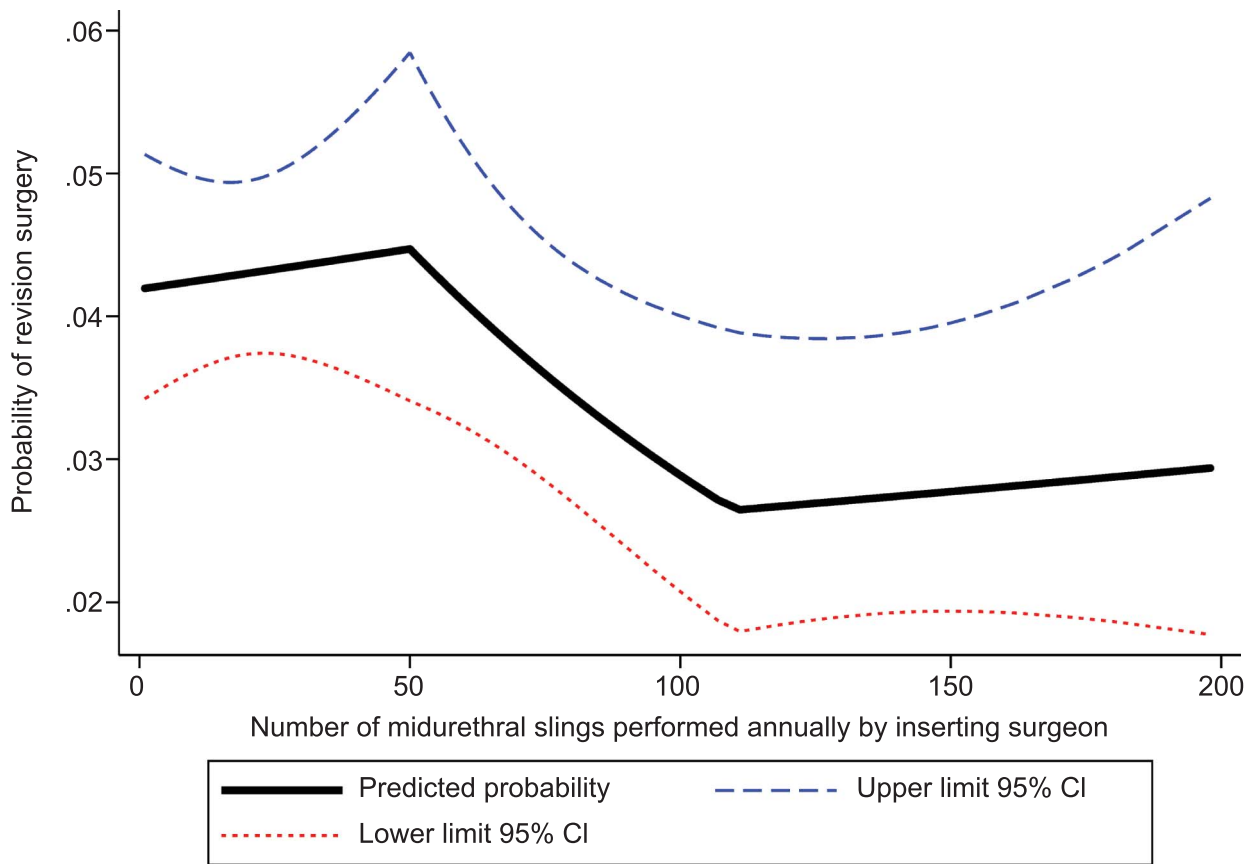
urethral dilation, retropubic or transvaginal urethrol-ysis, or repair of a urethrovaginal fistula. Our definition excludes mesh exposures that were excised in a physi-cian office. Those were not the outcomes of interest of this study because mesh exposures that can be handled as a clinic visit result in significantly less disruption to patients and the healthcare system. Appropriate Cana-dian Classification of Health Intervention codes repre-senting these surgical outcomes were determined through review of the Canadian Classification of Health Intervention coding manual by a content expert (a female pelvic reconstructive surgeon), discussions with health information coders, and review of the frequency of Canadian Classification of Health Intervention codes found in a study related to mesh complications in Ontario, Canada.<sup>8</sup> The Canadian Classification of Health Intervention codes used to define exposure and outcomes are shown in the Tables 1 and 2.

Age and concomitant surgeries were identifiable. Age was modeled continuously. Procedures such as hysterectomy, vaginal vault suspension, and vaginal wall repairs for pelvic organ prolapse (POP) were identified through Canadian Classification of Health Intervention codes on the same encounter. Cases using permanent polypropylene mesh for POP were identified and censored from analysis because it would not be possible to determine whether mesh revision or removal was related to either the midure-thral sling procedure, the POP procedure, or both.

Hospital of insertion was anonymized but classifi-able as rural, urban, or academic facility type. Academic centers were defined as those with surgeons who were fellowship-trained in female pelvic medi-cine and reconstructive surgery and associated with a university providing postgraduate residency training in obstetrics and gynecology or urology or a fellow-

ship in female pelvic medicine and reconstructive surgery or both. Urban centers were defined as nonuniversity hospitals occurring in the five most populated incorporated urban municipalities (a “city”) in Alberta, each with a population greater than 60,000. All other facilities were considered rural. The attending surgeon who inserted the midurethral sling was identified through a unique anonymized identifier that remains linked to an individual practi-tioner throughout the lifespan of his or her career. This allowed determination of all midurethral sling procedures performed by the same surgeon within 1 year and creation of a variable representing number of midurethral slings inserted according to the year of insertion. As such, midurethral sling procedures per-formed by the same surgeon at various points in time would have differing values for the surgeon’s annual volume based on the number of procedures per-formed in the entire calendar year before the specific case. Base specialty (gynecology vs urology) is identi-fied in this dataset, but subspecialty designation of fellowship training in female pelvic medicine and reconstructive surgery is not.

Descriptive statistics were used to present pop-ulation characteristics per year of the cohort (Table 3). Crude proportion of midurethral sling procedures re-sulting in revision surgery was determined using the number of individuals experiencing the outcome divided by the total number at risk who had under-gone a midurethral sling procedure. An individual contributed to the composite outcome only once (eg, if a woman underwent two mesh revision surgeries, only her first revision was counted). Amount of time each participant contributed was the interval between surgical date for midurethral sling insertion and the end of the dataset. A composite variable representing



**Fig. 1.** Probability of revision surgery by inserting surgeon's annual volume of midurethral sling procedures. Brennard and Quan. *Operative volume and risk of mesh sling revision. Obstet Gynecol* 2019.

outcomes of interest was created representing any mesh revision surgery. Presence or absence of these composite outcomes was used as event status, and the first occurrence was considered the event date.

Noncumulative rates (eg, annual rates) of revision surgery were calculated for each of the first 10 years after midurethral sling placement. Cumulative rates of outcomes were calculated for observation time points common to clinical trials to allow comparison of population data to other published studies. Determination of rates of revision surgery at each time point were calculated using only women who had contributed to the full interval (eg, a woman who had 4 years of follow-up contributed to risk in years 1, 2, 3, and 4 as well as the 3-year cumulative risk, but did not contribute to the 5-year cumulative risk).

Odds of revision by surgeon's annual volume was modeled using linear splines, given that a non-linear relationship was expected. To account for clustering of surgeons and variance between individual surgeons, multilevel mixed-effect logistic regression with random intercepts<sup>19</sup> was used. Loca-

tion and number of knots were determined by visual inspection of Lowess curves, and statistical evaluation of whether slopes before and after knots differed.<sup>20</sup> Evaluation for modification and confounding by surgeon's specialty, concomitant prolapse surgeries, hospital type, patient age, and duration of follow-up in the dataset was conducted. The most parsimonious model was determined as the one with the lowest Bayesian information criterion value.<sup>21</sup>

Sensitivity analyses restricting the multivariable modeling to patients at the 1-, 3-, and 5-year follow-up time points were performed. An additional sensitivity analysis was conducted censoring very low-volume surgeons who contributed a small volume of cases for a short interval of time (no more than 2 consecutive years and performed no more than 10 cases), because it was felt that these cases may represent teaching cases in which a more experienced surgeon guides a less experienced colleague on performance of midurethral sling placement. Data analysis was performed with Stata 15.

## RESULTS

We identified 21,028 women as receiving midurethral sling for urinary incontinence during the 13-year cohort, with 1,517 experiencing a concomitant mesh procedure for POP. Those cases were censored from the final dataset leaving a sample size of 19,511 women.

Mean follow-up was  $6.78 \pm 3.59$  years. Median age, proportion of women undergoing concomitant prolapse surgery, proportion of slings inserted by each surgical specialty, and median number of midurethral slings inserted each year per practitioner are shown in Table 3.

The crude proportion of mesh revision surgery for complications in the entire cohort without adjustment for follow-up period was 3.95% ( $n=770$ , 95% CI 3.68–4.23). Of these, 144 women required (0.74%, 95% CI 0.62–0.86) two or more mesh revision surgeries in the interval. The first revision surgery for complications occurred at median of 1.14 years (IQR 0.32–3.04). Noncumulative and cumulative rates of revision surgery are shown in Table 4.

Lowess curves suggested natural transitions in the odds of the outcome at volumes of 25, 50 and 110 cases per year. A two-knot model was adopted to prevent overfitting after comparison of slopes before and after the first knot showed no significant difference ( $P=.806$ ).

Starting model included annual surgeon volume, patient age, concomitant prolapse surgery, duration of follow-up, surgeon specialty, hospital type with random intercepts on unique surgeon, and hospital IDs. Comparison of Bayesian information criterion and the estimates of random effects indicated that an intercept on insertion hospital ID did not improve the model's goodness of fit and it was removed.

The most parsimonious model by lowest Bayesian information criterion score would have excluded duration of follow-up, but a decision was made to adjust for this, because it seemed biologically plausible to have a relationship with the outcome and it almost reached statistical significance. McFadden's  $\rho^2$  for the final model was 0.383, indicating excellent goodness of fit.<sup>22,23</sup>

For patient-related risk factors, only concomitant prolapse surgery was associated with revision. The fixed-effects model common to all surgeons indicates that, for those surgeons inserting 1–50 midurethral slings per year, odds of revision surgery did not change per additional procedure performed. In the range of 51–110 midurethral sling procedures per year, odds of requiring revision surgery did decline (odds ratio per additional case of 0.99, 95% CI 0.98–0.99,  $P=.024$ ). However, after performance of 110 cases per year, odds of subsequent revision surgery did not further improve. For ease of

**Table 6. Crude Rates of Revision Surgery Over Range of Annual Volume of Midurethral Slings Inserted**

Range of Annual MUS Cases	% (95% CI)
1–10	4.82 (4.06–5.67)
11–20	5.12 (4.20–6.17)
21–30	4.23 (3.40–5.20)
31–40	3.98 (3.05–5.10)
41–50	4.65 (3.38–6.21)
51–60	4.73 (3.25–6.21)
61–70	3.83 (2.58–5.46)
71–80	3.68 (2.72–4.87)
81–90	3.66 (2.25–5.61)
91–100	3.23 (2.22–4.52)
100–110	2.68 (1.08–5.45)
110 or more	2.78 (2.34–3.27)

MUS, midurethral sling.

interpretation, Table 5 expresses these findings in incremental units of 10 additional cases per year, and these findings have been converted to the probability scale and are shown in Figure 1. Crude risks of revision surgery over interval ranges of annual operative volumes are shown in Table 6.

Two hundred thirty individual surgeons contributed cases to this dataset, representing 190 gynecologists and 40 urologists. Median number of midurethral sling procedures per surgeon each year is shown in Table 3. Ninety-seven surgeons were considered very low volume. Of the 133 surgeons who contributed the majority of cases, 104 were gynecologists and 29 were urologists. Thirty-one surgeons were considered high-volume (more than 50 cases per year), and this group was comprised of both specialties. There was no differential loss to follow-up between low- and high-volume surgeons. Results of the sensitivity analyses were consistent across these models (Table 7).

## DISCUSSION

Revision surgery occurs for a small proportion of women undergoing midurethral sling placement. In our cohort, the 10-year revision rate was approximately 5%. This is comparable with results using U.K. National Health Service data,<sup>6</sup> American data,<sup>7</sup> and Canadian data from the province of Ontario.<sup>8</sup> Documenting mesh reoperation rates from a population-based perspective is important because estimates of complications from registries such as the FDA MAUDE database are felt to be biased.<sup>24</sup>

Our documentation of low rates of revision for midurethral sling procedures is important in the current medical-legal climate, given the intense worldwide media coverage of the FDA, Health

**Table 7. Sensitivity Analyses at 1, 3, and 5 Years' Complete Follow-up**

Variable	OR (95% CI)	P
1-y follow-up		
Duration of follow-up (y)	1.02 (1.00–1.05)	.057
Concomitant native tissue prolapse surgery	1.23 (1.04–1.46)	.018
Annual volume of MUS inserted		
1–50 cases	1.00 (0.99–1.01)	.787
51–110 cases	0.99 (0.98–1.00)*	.030
110 or more cases	1.00 (0.99–1.01)	.816
3-y follow-up		
Duration of follow-up (y)	1.01 (0.99–1.06)	.550
Concomitant native tissue prolapse surgery	1.24 (1.04–1.48)	.018
Annual volume of MUS inserted		
1–50 cases	1.00 (0.99–1.01)	.552
51–110 cases	0.99 (0.98–1.00)*	.047
110 or more cases	1.00 (0.99–1.01)	.966
5-y follow-up		
Duration of follow-up (y)	1.04 (1.00–1.08)	.064
Concomitant native tissue prolapse surgery	1.27 (1.05–1.53)	.012
Annual volume of MUS inserted		
1–50 cases	0.99 (0.99–1.00)	.109
51–110 cases	0.99 (0.99–1.00)*	.044
110 or more cases	1.00 (1.00–1.01)	.108
Model with very low-volume surgeons removed		
Duration of follow-up (y)	1.00 (0.99–1.00)	.062
Concomitant native tissue prolapse surgery	1.21 (1.02–1.44)	.033
Annual volume of MUS inserted		
1–50 cases	1.00 (0.99–1.01)	.771
51–110 cases	0.99 (0.98–0.99)	.029
110 or more cases	1.00 (0.99–1.01)	.813

OR, odds ratio; MUS, midurethral sling.

\* Rounded up, but 95% CI does not cross 1.00 at three decimal places.

Canada, and National Health Service warnings and subsequent class-action lawsuits from women who have experienced complications. Presentation of surgical risk is not well represented by the lay media, and the internet is rife with narrative anecdotes.<sup>25</sup> This has resulted in a significant amount of fear among patients considering midurethral sling surgery. Precise rates produced by this study can provide some perspective. When the low rates of revision surgery after midurethral sling placement are contrasted against the much higher rates reported for vaginal mesh procedures for POP,<sup>26</sup> our study also supports suggestions<sup>8</sup> that warnings related to pelvic mesh should very specifically separate recommendations and device concerns regarding mesh used for POP compared with that used for SUL.

Our study's characterization of how a surgeon's annual case volume is associated with the risk of revision surgery suggests a nonlinear relationship. In our model, a threshold of annual surgical cases exists where the rates of revision surgery are comparable. After this threshold, the risk of subsequent surgery begins to decline. Finally, a plateau occurs where risk

of revision no longer seems to improve. These results suggest that surgeons' operative experience plays an important role in a patient's outcome. Our study supports the recommendations of experts and regulatory bodies that surgeons placing mesh procedures should receive specialized experience and training.<sup>7,8,27–29</sup> Furthermore, it suggests outcomes could be improved by supporting low-volume surgeons to achieve equivalent outcomes through supplemental experience, or concentrating midurethral sling procedures to those who perform significant annual volumes.

Concomitant nonmesh surgery for POP was also associated with an increased risk of revision surgery. This finding is in agreement with other studies.<sup>7,8,26</sup> It has been suggested this is due to additional dissection, trauma, and changes to anatomy that occur as a result of additional vaginal procedures. Given the reproducibility of this finding, surgeons may want to consider separating surgeries into two stages, waiting to perform midurethral sling placement until the patient is completely healed from POP surgery.

Although it has been suggested that the nature of gynecologic and urologic training and practice could



lead to differences in outcomes,<sup>8,30</sup> our study suggests no significant difference in rates of revision exist between the two specialties. For both specialties, patients of higher volume surgeons were less likely to experience revision surgery. This finding is important, as policies and credentialing standards regarding midurethral sling procedures should be uniformly applied to each discipline.

Inpatient administrative data have been used previously to study long-term risks of midurethral sling placement.<sup>6-8</sup> The procedural codes used in our study are the same as those of Welk et al,<sup>8</sup> given that the province of Ontario uses the same national Canadian coding guidelines as Alberta.<sup>11,12</sup> However, procedural coding in the National Health Service<sup>6</sup> and American data sources<sup>8</sup> used different frameworks. Despite this, estimates of revision rates are similar. As with previous studies we examined risk of revision surgery using the cumulative incidence,<sup>6,8</sup> rather than Kaplan-Meier curves,<sup>7</sup> for ease of interpretation. Additionally, we reported noncumulative risk at each postoperative year to determine which windows held the greatest risk of revision. Prior work has examined risk factors for revision using Cox proportional and Fine-Gray hazard models<sup>6-8</sup> treating the outcome as survival data with competing risk. These models report hazard ratios for the variables of interest and are linear in nature. Our model addresses similar questions to these prior works but allows for nonlinear relationships to exist and graphical depiction of the model. This allows a detailed understanding of how risk of revision changes along a continuum of surgical volume. Our study, in addition to previous work using administrative data,<sup>6-8</sup> support that the use of de-identified, patient-level data routinely collected for administrative and claims use is feasible and powerful to study uncommon outcomes after midurethral sling procedures. Furthermore, the relationship that has previously been suggested between revision surgery and surgeon operative volume is robust.

One of the strengths of our study is the population-based approach and large size allowing more precise and generalizable estimates of rates and risk factors for revision surgery than those from clinical trials. Comparable rates of revision in our study and those from other health systems indicate that quality and performance of midurethral sling procedures are similar across different healthcare delivery models, and that results from one system can be generalized to another. However, the thresholds and plateaus determined by this study should not be taken as absolute. Modeling physician annual volume in a nonlinear context is novel, and this requires further exploration in other healthcare settings, as the nature of clinical training for surgeons in other countries

may result in different relationships and cut offs. Another limitation of our study is that we are not able to explore, in depth, potential reasons that the risk of repeat surgery begins to plateau along the continuum of surgical volume. It may be that some suboptimal outcomes occur stochastically and cannot be predicted or prevented. It is also plausible that surgeons performing high annual volumes of midurethral sling procedures have a higher proportion of complex patients, such as those with both SUI and preexisting voiding dysfunction or chronic pain conditions, which may predispose those cases to higher rates of revision. Granular case information such as this are not captured by the majority of administrative data sets. This type of measurement information bias is a known limitation of secondary use of administrative data and would have the effect of bias towards the null. As such, it is possible that improvement in risk of revision surgery after 110 annual cases per year does occur, but we are unable to distinguish it.

In conclusion, rates of revision surgery after midurethral sling placement are low and do not differ between gynecologists and urologists. However, patients of higher volume surgeons experience lower risks of revision, and those who have concomitant prolapse surgery appear to have an increased risk.

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