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# Evaluation of the Effect of Hospital and Physician Factors on Likelihood of Revision After Mid-Urethral Sling Placement

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# Evaluation of the Effect of Hospital and Physician Factors on Likelihood of Revision After Mid-Urethral Sling Placement

by

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## Abstract

**Objective:** To estimate rates of revision surgery after insertion of mesh midurethral slings (MUS) and explore if healthcare attributes such as physician specialty, annual operative volume, or hospital type are risk factors for this outcome.

**Methods:** This study used a population-based retrospective cohort of women who underwent MUS insertion over a 13-year interval (2004–2017) in Alberta, Canada. The main outcome was subsequent surgery for revision of MUS, defined by a composite of surgical procedures. Exposures included annual number of MUS procedures performed by the surgeon, facility type, surgeon specialty, patient age, and concomitant prolapse repair. Mixed-effects logistic regression utilizing linear spines was used to test the a priori hypothesis that annual surgical volume would be inversely related in a non-linear fashion to risk of revision.

**Results:** In a cohort of 19,511 women, cumulative rates of revision surgery were 3.36% (95% CI 3.06–3.68) at 5 years and 4.57% (95% CI 4.00–5.21) at 10 years. The first year after MUS insertion was the most vulnerable window, with 0.39% (95% CI 0.31–0.49) undergoing revision within 30 days and 2.05% (95% CI 1.85–2.26) within a year. Concomitant prolapse repairs (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 = 0.991 per case, 95% CI 0.983–0.999; OR = 0.91 per 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.

**Conclusions and relevance:** Within 10 years, nearly 1 in 20 women underwent revision surgery after MUS insertion. Physician annual surgical volume appears to be a risk factor, with a decline in risk of revision surgery occurring at an annual threshold of >50 cases. Given that annual case volume is a potentially modifiable risk factor, development of policies regarding minimum

caseload parameters for surgeons performing MUS procedures may hold potential to improve the quality of MUS surgery.

## Preface

This thesis is original, independent work by the author, Erin Brennand. Portions of Chapters 1 to 5; Tables 1–5, A1, and A2; and Figure 2 are used with permission from E. Brennand and H. Quan (2019),[1] of which I am an author. The study was covered by Ethics Certificate number 18-0811, issued by the University of Calgary Conjoint Health Ethics Review Board on June 12, 2018.

## Acknowledgements

Thank you to Dr. Hude Quan, my supervisor, and Dr. Amy Metcalfe and Dr. Mingkai Peng, my thesis committee members, for their help and advice during this degree. I consider myself very fortunate to have worked with such a supportive and accomplished team.

This thesis has been professionally edited.

## Dedication

This work was inspired by the women who have trusted me with their medical care. Their stories and experiences are the driving force in my journey to make meaningful improvements to the practice of gynecology.

Dedicated to my three children, Benjamin, Alexandra, and Frankie—may knowledge and truth always be your guiding light.

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## List of Abbreviations

AHS: Alberta Health Services

AIVA: Annual Information Verification and Attestation

BIC: Bayesian information criterion

CCI: Classification of Health Intervention

CIHI: Canadian Institute for Health Information

FDA: Food and Drug Administration

ICD-10-CA: International Classification of Disease, Version 10, Canadian

LOWESS: locally weighted scatterplot smoothing

MAUDE: Manufacturer and User Facility Device Experience

MUS: mesh midurethral sling

NHS: National Health Service

POP: pelvic organ prolapse

SUI: stress urinary incontinence

TDF: theoretical domains framework

ZCDH: Zone Clinical Department Head

## Chapter 1: Introduction

Stress urinary incontinence (SUI), the involuntary loss of urine with activity, affects 1 in 4 women by age 80.[2] While most epidemiologic studies use patient reported symptoms to define incidence and prevalence,[3,4] a standard epidemiologic definition does not exist.[5] The questionnaire tools used by research groups are not standardized, which likely contributes to variation in estimates.[4] The standardized definition of stress urinary incontinence endorsed by the International Continence Society is the "complaint of involuntary leakage on effort or exertion, or on sneezing or coughing" with physical examination to observe "involuntary leakage from the urethra, synchronous with exertion/effort, or sneezing or coughing."[6] This physical examination can be a pelvic exam with a naturally full bladder to observe leakage through the urethra, or an invasive diagnostic test called Urodynamics where a patient is put through an artificial bladder filling cycle using bladder and rectal catheters. The objective documentation is considered essential for a clinical diagnosis of SUI.[6] The subjective patient reporting of symptoms for epidemiologic research regarding SUI does raise the possibility of discrepancy between patient perceptions of their incontinence and a clinician's diagnosis. However, studies have shown high concordance between patient report and clinician evaluation when it comes to both the diagnosis of stress incontinence and severity of incontinence.[7] As such, use of patient questionnaires makes epidemiologic study of SUI feasible.

SUI is usually a consequence of the impact of childbirth on the pelvic floor musculature and is associated with both diminished overall and condition-specific quality of life measurements.[8,9] Women with SUI are more likely to have anxiety and depression,[10,11] hold a negative self body-image, report low self-esteem,[12] and experience sexual and relationship dysfunction.[11] While non-surgical options such as physiotherapy and a pessary support device

exist, cure rates are highest with a surgical approach.[13,14] It is estimated that 12% of women will undergo surgical correction of this type of pelvic floor damage in their lifetime.[15,16]

The original gold standard surgery for SUI was an open retropubic colposuspension.[17] This is a procedure performed through a laparotomy incision, which sutures the tissue below the neck of the bladder and adjacent to the upper urethra and affixes them to the pubic bones. This mechanism lifts the tissue cranially and dorsally, and results in an increase of the closure pressure of the urethra. Open surgery requires a 6- to 8-week recovery period and post-operative length of stay of 1 to 4 days.

In 1996, Ulmsten et al. described a revolutionary technique for treatment of SUI where a mesh "sling is only loosely placed – without elevation – around the urethra."[18] This approach could be performed as an outpatient procedure,[19] resulting in less post-operative discomfort and a faster return to work. With an objective cure rate of 90%, this technique was shown to be equivalent to retropubic colposuspension in terms of post-operative cure.[17,19] This technique came to be known as the midurethral sling (MUS) and became commercially available as surgical kits that included a small strip of plastic mesh and a trocar device, which tunnels the strip under the urethra to provide support. MUS procedures quickly became the new gold standard surgical treatment, and only 10 years after their introduction over 1.2 million had been implanted worldwide.[20]

While early adopters of MUS kits were generally those who performed high volumes of pelvic floor reconstructive surgery (generally considered to be female pelvic reconstructive surgeons), marketing to North American and European physicians through print journal ads, industry representatives at scientific meetings, expert opinion sessions, and paid "training" seminars was aggressive. This resulted in an increased uptake of the procedure by generalist

surgeons and increased availability and performance of the procedure. In the window of 2004–2008, the use of mesh devices such as MUS in North America was at its peak.[21]

Introduction of MUS procedures in Alberta, Canada, occurred in 2000, and the provincial experience with the procedure paralleled the American experience.[21] It was first performed by subspecialty-trained urogynecologists in Edmonton and Calgary. The perceived ease of the procedure and large demand for treatment of incontinence led to the rapid spread of MUS procedures into generalist gynecologist practice and smaller peripheral hospitals across the province.

Complication rates reported in clinical trials were very low, in the range of 1 to 6%.[22,23] Trial data such as this contributed to the original approvals of MUS by regulatory bodies such as the United States' Food and Drug Administration (FDA) and Health Canada.[22,23] However, over time, reports of erosion of surgical mesh into adjacent structures such as the vagina and bladder, injury to the bowel, and chronic pelvic and vaginal pain began to accumulate in the FDA Manufacturer and User Facility Device Experience (MAUDE) database. These complications generally require additional surgery to remove a portion or all of the MUS. Treatment may require more than one re-operation event, and cure through revision surgery is not guaranteed.

The MAUDE database reports led to the FDA issuing an advisory regarding the use of pelvic mesh in 2008.[24] Health Canada followed suit in 2010.[25] These warnings resulted in increased attention from patients and media regarding suboptimal outcomes after MUS procedures and featured heavily in landmark litigations against manufacturers of MUS devices. The sensationalized reporting of the large monetary awards in these cases, as well as online narratives of personal injury,[26] has led to a negative public perception of mesh devices such as MUS.[27] While multiple professional bodies have published position statements on the use of

vaginal mesh meant to quell the concerns of patients,[28,29] there is evidence that women remain fearful of MUS procedures and that fewer women are electing to have incontinence treated.[30]

To improve the confidence of women seeking SUI treatment, complication rates associated with MUS procedures should be examined on a population level. This is because estimates from databases such as MAUDE are known to be biased[31] and the rates from randomized clinical trials may not apply to real world practice in a general population 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.

While the complication rates associated with MUS are expected to be low, study of these rare complications in a population-based dataset may allow the identification of opportunities to improve the provision of MUS procedures. This is imperative, as the existing model of providing MUS surgeries has resulted in regulatory advisories, lawsuits, and, most importantly, negative outcomes for women. Improving care going forward is required to restore patients' confidence in MUS surgeries. Furthermore, identification of risk factors for revision surgery is important, as it allows personalized pre-operative counselling or avoidance of surgery in high-risk cases.

Prior work to identify risk factors for complications has shown that patient factors such as age, comorbidities, concomitant prolapse,[32,33] body mass index,[34,35] and frailty[32,36,37] are associated with suboptimal outcomes in the gynecologic literature. But while identifying these patient risk factors can help in recognizing high-risk patients, they hold little opportunity for improvement in patient care. This is because it puts an onus on the patient to improve their own risk factors, many of which (such as smoking status or body weight) are not easily optimized. Furthermore,

some cannot be changed at all (e.g., age, concomitant medical conditions). This leaves denial of surgery as one of the only patient-related approaches to decrease post-operative complications.

In contrast, identification of factors within the healthcare system that influence complications holds the potential to optimize delivery of care to all patients, given that these factors should be modifiable. Targeting health system factors also has the benefit of placing the responsibility for improvement with the healthcare system and surgical providers, rather than putting the onus on the patient. This can be done through development of policies and procedures and medico-cultural changes.

Institution-related factors such as hospital volume, facility type (academic vs. community), and location (urban vs. non-urban) have been associated with patient outcomes[38,39,40,41] in various surgical disciplines, including gynecology. These factors could reflect variations in peri-operative and post-procedure care, which can result from healthcare professionals' limited exposure to similar procedures, the continuing medical education available to healthcare professionals in differing settings, and differences in healthcare professionals' knowledge spread related to the size and turnover within surgical groups.

Work examining practitioner-related factors specific to MUS procedures have suggested that risk of revision surgeon may be different between the two surgical specialties that provide these procedures (gynecology vs. urology)[42] and that a surgeon's annual procedural volume[33,43] is associated with this risk, with lower volume practitioners experiencing higher rates of revision. Prior studies exploring the relationship of a gynecologic surgeon's procedural volume and surgical outcomes have done so by dichotomizing volume into very low volumes of one to two procedures per year versus more than two cases per year,[43] comparing the top quartile to the rest,[33] or establishing thresholds based on expert opinion.[37,44] Modelling using these approaches

suggests a relationship between surgical volume and outcomes exists. However, the nature of this relationship is not fully characterized. The relationship may be linear, where the experience of each additional case reduces the risk of complications, or it may be more complex with occurrence of thresholds and plateaus along the continuum of annual surgical volume. Information obtained by exploring the relationship in a non-linear context would be useful for the development of policies that may be related to minimum annual numbers for surgeons providing MUS procedures.

Administrative health data from the province of Ontario has been used to study rates of revision of vaginal mesh used to treat stress urinary incontinence[33]. In a population based cohort of >59,000 individuals with 10 years of follow-up, associations with surgeons annual clinical volume, hospital type, simultaneous hysterectomy and multiple mesh based procedures were found. In addition to producing data suggesting that within Canadian health care, surgeon risk factors influenced revision, this study produced a list of procedural codes used in Canadian administrative health data that could represent vaginal mesh procedures (including MUS) and subsequent revision surgeries which could be used as a framework for future studying SUI surgeries using administrative health data.

The population-based administrative data collected routinely by Alberta Health Services is well suited to describe the real world complication rates of MUS procedures and explore healthcare system–related risk factors for complications after MUS insertion. In the province of Alberta it is mandated that all inpatient admissions, including surgical visits, are reported to the Discharge Abstract Database, and all outpatient visits and day surgery procedures occurring within an Alberta Health Services facility are reported to the National Ambulatory Care Reporting System (prior to 2010, they were reported to the Ambulatory Care Classification

System). Surgeons and hospitals are represented by unique anonymized identifiers that remain linked to the practitioner or facility for their duration within these data sources. Surgical procedures are identified through Canadian Classification of Health Intervention (CCI) coding,[45] and the diagnostic information associated with these procedures is recorded using the International Classification of Disease, 10th Revision, Canada (ICD-10-CA).[46]

Given increasing global concern about pelvic mesh, it is important to accurately determine rates of revision for MUS and thoroughly model impact of surgeon experience on this outcome. This information is timely as it can be used for the development of policies and procedures aimed at improving patient outcomes after MUS surgery. It was the goal of this thesis work to use Alberta's administrative health data to 1) determine rates of mesh revision surgery after MUS insertion and 2) examine how health system factors, including surgeon's annual surgical volume, specialty, and hospital type, impact the risk of revision.

## Chapter 2: Methods

### Study Design and Setting

Ethics approval was received from the Conjoint Health Ethics Review Board, University of Calgary (REB180881). A 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, a Canadian province with a population of approximately 4 million. Healthcare in this setting is delivered through a universal, single-payer model and covers all individuals with Canadian citizenship, permanent resident status, or a valid work or study permit. The dataset captured all members of the Alberta population eligible to receive healthcare. Waitlists in Alberta have historically been shorter than neighbouring provinces, meaning it is unlikely an Alberta resident would have surgery out of province. As a result, all surgical procedures subsequent to an MUS insertion would be captured unless the patient emigrated afterward. While 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 a 1.5% emigration and 2.9% death rate in a comparable patient population over a 20-year period.[33]

### Data Sources and Linkage

This study collected data from three databases containing person-level information on exposure, outcomes, and co-variates that was linked by unique personal health number and gender. The component datasets came from the Discharge Abstract Database, which captures all inpatient surgical procedures and subsequent hospital admissions (2004–2017), and two same-day surgery databases, the National Ambulatory Care Reporting System (2010–2017), and the Ambulatory Care Classification System (2004–2009). These datasets adhere to ICD-10-CA[46] and

CCI[45] standards of coding. In general, the diagnostic and procedural coding of these sources has been validated as highly accurate.[47,48,49,50] Accuracy within these sources is known to vary by diagnosis and procedure performed. Existing work has shown the accuracy of gynecologic procedures to be quite high.[49] CCI codes for removal of the ovary had a Kappa of 0.99 (0.97 to 1.00), Sensitivity of 0.99 (0.95 to 1.00) and Specificity of 0.98 (0.93 to 1.00) in a re-abstraction study of the 10 hospitals that provide case costing information in the province of Ontario.[49] The other gynecologic procedure evaluated, hysterectomy, was been shown to have a Kappa of 0.97 (0.94 to 0.99), Sensitivity of 0.93 (0.86 to 0.98) and Positive Predictive Value of 1.00 (0.96 to 1.00). Evaluating the quality of coding for hysterectomy procedures at a more granular level determined that agreement existed for the mode of surgery (vaginal, laparoscopy or open laparotomy) in 84 of 85 cases.

While validation of CCI coding for MUS procedures has not been specifically performed, it is expected that similar accuracy exists given that the CCI code associated with MUS describes the procedures both anatomically and with the manufacturer's trade names (TVT, Monarc, Sparc) in the coding standards manual. Additionally, no homophone or homograph procedures exist to cause confusion when cross referencing the coding standards. To determine the CCI codes used to define MUS cases, we conducted a literature review and found only one study from the province of Ontario utilizing administrative health data to study MUS procedures. Nine 9 CCI codes were suggested. These specific 9 codes were reviewed by 3 pelvic reconstructive surgeons at the pelvic floor clinic to determine if they assessed to specifically describe MUS procedures. Additionally the rubrics for Therapeutic Interventions on Vagina (1.RS.^^.^^), Therapeutic Interventions on Bladder Neck (1.PL.^^.^^) and Therapeutic Interventions on the Urethra (1.PQ.^^.^^) were reviewed by EB order to ensure no additional CCI codes that could

represent MUS procedures could be found. Health information coders at the Foothills Hospital then reviewed the MUS code list for feedback as to whether the proposed list was felt to be exhaustive. The final list of CCI codes used to define MUS cases in this data set was the same as those proposed by Welk et al.[33] However only 7 of the 9 codes were found to be in use in our dataset. These are shown in Table A1.

Given that MUS revisions are less commonly performed, and could be at risk of inaccurate coding we validated the CCI coding algorithms for mesh revision cases that had been suggested by Welk et al. [33] Five female pelvic reconstructive surgeons were interviewed (by EB) regarding their practice of describing MUS revision surgeries in operative dictations and the wording compared to the CCI list suggested by Welk.[33] The CCI rubrics for Therapeutic Interventions on Vagina (1.RS.^^.^^), Therapeutic Interventions on Bladder Neck (1.PL.^^.^^), Therapeutic Interventions on the Bladder (1.PM.^^.^^), Therapeutic Interventions on the Urethra (1.PQ.^^.^^) and Therapeutic Interventions on the Chest and Abdomen (1.SZ.^^.^^) were reviewed to identify any additional CCI codes that could represent MUS revision procedures. The final list included 31 codes,[33] which were again reviewed with health information coders who confirmed these codes represented an exhaustive list of possible CCI codes reflecting MUS revision surgeries. A 3 year sample (2015-2017) of "true positive" MUS revision surgeries (n=65) performed by three pelvic reconstructive surgeons at the Pelvic Floor Clinic in Calgary, Alberta was obtained to validate these CCI codes. After reviewing these charts and their matching DAD/NACRS records, it was determined sensitivity (93.8%, $n$ = 61/65). These cases (95% CI 85.0-98.3%) had a CCI code in the administrative record that accurately described the revision surgery. A total of four different CCI rubrics were identified in this sample (Table 1), and they correspond to the four CCI codes most commonly associated with revision after MUS

in the study from Ontario.[24] In the four cases that did not have an appropriate CCI code reflecting MUS revision, the cases involved a concomitant repair of the anterior vaginal wall for prolapse (1.RS.80.^^, Repair vagina). It is possible that when the cases were coded either the mesh removal portion of the surgery was missed due to the fact that multiple procedures were performed, or that the coder thought 1.RS.80.^^ encompassed the "repair" of the sling. Of the original 31 codes proposed by Welk et al.[33] as defining revision after index MUS sling[33], 11 were found in our final dataset (Table A2).

**Table 1. CCI codes associated with mesh revision surgeries at Foothils Hospital, Calgary**

| CCI Code | Description | Number of Cases |
|---|---|---|
| 1.PL.55.^^ | Removal of device bladder neck | 17 |
| 1.PL.54.^^ | Management of internal device, bladder neck | 31 |
| 1.PQ.72.^^ | Release, urethra | 7 |
| 1.RS.55.^^ | Removal of device, vagina | 6 |

### Study Size

A study window of 2004 to 2017 was specifically chosen because MUS insertion in Alberta began in 2002, after a formal evaluation regarding safety and economics. It was expected that from 2002 to 2003, the number of MUS cases was low. The small number of surgeons performing MUS procedures in the first two years could also result in their inadvertent identification. However, by 2004, MUS insertion was widespread, making identification of individual surgeons unlikely. Additionally, it was expected that health information coders who submitted CCI codes to the data sources may have required time to become accustomed to the

procedural codes representing MUS. Finally, a transition in the framework for procedural coding occurred from 2001 to 2006. The Canadian Classification of Diagnostic, Therapeutic and Surgical Procedures, which was comprised of 3,500 unique codes, was replaced by the CCI, which provided richer data through over 18,000 codes.[51,52] This transition was completed in Alberta by 2002, and health information coders would have adjusted to the new framework by 2004. Thus, beginning the study window in 2004 was expected to translate into accurate coding.

### Participants

Surgical procedures are recorded in all three datasets using CCI codes. Individuals were selected for inclusion if they were coded as undergoing a mesh-based urethral sling procedure within the study timeframe. CCI coding maps MUS procedures to certain qualifier codes that represent "use of synthetic tissue, such as tension free vaginal tape (TVT)." These MUS procedures could be performed in isolation or in combination with other surgical procedures. Exclusion criteria was an individual recorded as having a mesh-urethral sling procedure in the 2 years prior to our study interval, thus creating a washout period ensuring none of the revisions were from procedures outside our study window and thus attributed to the incorrect surgeon.

After identification of an MUS procedure, the first occurrence of that CCI code was considered the index procedure and date. All available data on hospital readmission or day surgeries that occurred subsequent to the index MUS was obtained for each individual. While CCI codes can determine if route of placement for mesh sling procedures were per orifice (vaginal) surgeries, laparotomy, or laparoscopy, the anatomic variant of sling (retropubic vs. transobutator) and device manufacturer is not identifiable.

### Variables

Exposure was first occurrence of a MUS procedure (Table A1). Outcome of a subsequent surgery for sling complications was a binary outcome defined by CCI codes representing removal or revision of implanted surgical devices or mesh, removal of a urethral foreign body, urethral dilation, retropubic or transvaginal urethrolysis, or repair of an urethrovaginal fistula (Table A2). This definition excludes mesh exposures that were excised in a physician office. Those were not the outcomes of interest of this study because mesh exposures that can be handled in a clinic visit result in significantly less disruption to patients and the healthcare system. Appropriate CCI codes representing these surgical outcomes were determined through review of the CCI coding manual by a content expert (female pelvic reconstructive surgeon), discussions with health information coders, and review of the frequency of CCI codes found in a study related to mesh complications in Ontario, Canada.[33] CCI codes used to define exposure and outcomes are shown in the Appendix.

Age and concomitant surgeries were identifiable. Age was modelled continuously. Procedures such as hysterectomy, vaginal vault suspension, and vaginal wall repairs for pelvic organ prolapse (POP) were identified through CCI codes on the same encounter. Cases utilizing permanent polypropylene mesh for POP were identified and excluded from analysis as it would not be possible to determine if mesh revision or removal was related to the MUS procedure, POP procedure, or both.

Hospital of insertion was anonymized but classifiable as a rural, urban, or academic facility. Academic facilities were defined as those with fellowship-trained surgeons specializing in female pelvic medicine and reconstructive surgery associated with a university providing postgraduate residency training in obstetrics and gynecology or urology, a fellowship in female

pelvic medicine and reconstructive surgery, or both. Urban facilities were defined as non-university hospitals in the five most populated incorporated urban municipalities in Alberta, each with a population greater than 60,000. All other facilities were considered rural. The attending surgeon inserting the MUS was identified through a unique anonymized identifier than remains linked to an individual practitioner throughout their career. This allowed determination of all MUS procedures performed by the same surgeon within a year, and creation of a variable representing the number of MUS inserted per year. As such, two women who had MUS inserted by the same surgeon in different years could have a different value of their surgeon's annual surgical volume based on the calendar year prior to their surgery. The surgeon's base specialty (gynecology vs. urology) was identified in the datasets, but subspecialty designation of fellowship training in female pelvic medicine and reconstructive surgery was not.

### Statistical Analysis

Descriptive statistics were used to present population characteristics per year of the cohort (Table 2). Statistical comparisons in these characteristics over the year included in the cohort was performed to examine if differences existed, which would suggest a change in trends related to performance of MUS procedures over time.

The proportion of MUS cases resulting in a revision surgery was determined using the number of individuals who experienced this outcome divided by the total number who had undergone an MUS. An individual contributed to the outcome of revision surgery only once (e.g., if a woman underwent two mesh revision surgeries, only her first revision was counted). The amount of time each participant contributed was the interval between the surgical date for MUS insertion and the end of the dataset. The primary outcome variable representing outcomes of interest was created representing any mesh revision surgery. Frequency of each type of mesh

revision surgery is shown by the CCI code associated with the case in Table A2. Presence or absence of these composite outcomes were used as event status, and the date of first revision surgery was considered the event date.

Cumulative incidence of outcomes were calculated at 1 year time points to allow the results of this population based cohort to be compared to other published studies. In addition to reporting these results through a failure table, cumulative incidence was depicted graphically through a Kaplan Meier curve.

Odds of revision by surgeon's annual volume was modelled using linear splines, given that a non-linear relationship was expected. To account for clustering of surgeons and variance between individual surgeons, mixed-effect logistic regression with random intercepts[53] was used. Location and number of knots were determined by visual inspection of locally weighted scatterplot smoothing (Lowess) curves, and statistical evaluation of whether slopes before and after knots differed.[54] 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. Interaction terms included 1) surgeon's specialty and patient age, 2) surgeon's specialty and concomitant prolapse surgeries, and 3) patient age and concomitant prolapse surgeries. Likelihood ratio (LR) test was used for backward elimination to evaluate nested models to determine if leaving out interaction terms and covariables of the model significantly reduced the goodness of fit. This process was repeated until it was determined that no additional variables could be removed without a statistically significant loss of fit. The Bayesian information criterion (BIC) of models were also considered in the determination of the most parsimonious model.[55]

Sensitivity analyses restricting the multivariable modelling to patients at the 1, 3, and 5-year follow-up time points were performed. A sensitivity analysis removing surgeons who performed MUS procedures for 2 years or less and contributed less than 10 cases to the dataset was also performed.

To visually examine if the cumulative incidence survival curves were influenced by a surgeon's annual volume, cases were grouped by the breaks determined by the knots in our mixed-effects logistic regression model. Kaplan Meier survival curves for these groups where then compared by log rank test.

Data analysis was performed with Stata Statistical Software, Release 15 (College Station, TX: StataCorp LLC).

## Chapter 3: Results

### Participants and Descriptive Data

As part of the 13-year cohort, 21,028 women who received an MUS for urinary incontinence were identified, with 1,517 experiencing a concomitant mesh procedure for POP. Those cases were excluded from the final dataset, leaving a sample size of 19,511 women. Mean follow-up was 6.78 +/- 3.59 years. Median age, proportion of women undergoing concomitant prolapse surgery, proportion of slings inserted by each surgical specialty, and median number of MUS inserted each year per practitioner are shown in Table 2.

**Table 2. Descriptive characteristics of MUS cases by year of insertion**

| | | | | | | **Surgeon specialty** | |
|---|---|---|---|---|---|---|---|
| **Year** | ***n*** | **Proportion (%)** | **Age, years (*M* ± *SD*)** | **Concomitant POP surgery (%)** | **Median MUS per surgeon (IQR)** | **Urology (%)** | **Gynecology (%)** |
| Cohort | 19,511 | 100.0 | 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 |
| | | | $p < 0.001$* | $p < 0.001$^ | $p < 0.001$$ | $p < 0.001$^ | |

* ANOVA
^ Chi-square
$ Kruskal-Wallis

### Main Results

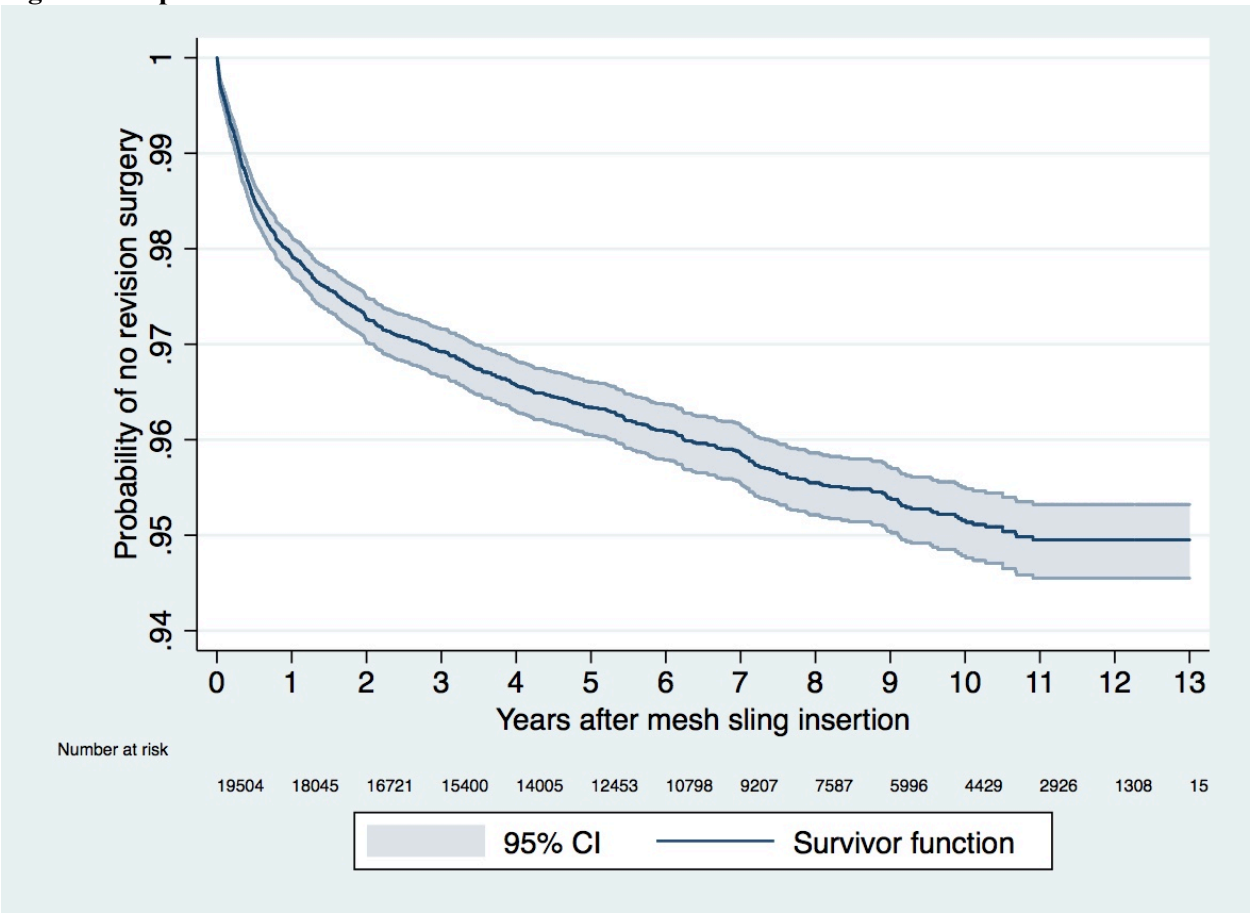
The crude proportion of patients in the cohort who received mesh revision surgery for complications without adjustment for the follow-up period was 3.95% ($n$ = 770, 95% CI 3.68–4.23). The first revision surgery for complications occurred at a median of 1.14 years (IQR 0.32–3.04). Of these, 144 women (0.74%, 95% CI 0.62–0.86) required two or more mesh revision surgeries in the interval. Women who underwent multiple revision surgeries were slightly younger than those who did not (50.8 ± 11.3 vs. 52.8 ± 11.5 years, p=0.023). However, they were not more likely to have undergone concomitant prolapse surgery (0.73% of those without POP surgery vs 0.57% of those that did, p=0.25).

Cumulative incidence of revision surgery are shown in Table 3 and visually depicted by a Kaplan Meier survival curve in Figure 1.

**Table 3. Cumulative incidence of revision surgery**

| Time interval after MUS insertion | Number of individuals at risk | Individuals censored | Number of mesh revisions | Cumulative Incidence (95% CI) |
|---|---|---|---|---|
| 0-1 year | 19511 | 1072 | 394 | 2.08% (1.88 - 2.29) |
| 1-2 years | 18045 | 1204 | 120 | 2.75% (2.53 - 2.99) |
| 2-3 years | 16721 | 1264 | 57 | 3.09% (2.85 - 3.36) |
| 3-4 years | 15400 | 1342 | 53 | 3.44% (3.19 - 3.72) |
| 4-5 years | 14005 | 1520 | 32 | 3.68% (3.41 - 3.96) |
| 5-6 years | 12453 | 1625 | 30 | 3.92% (3.64 - 4.23) |
| 6-7 years | 10798 | 1567 | 24 | 4.16% (3.86 - 4.47) |
| 7-8 years | 9207 | 1592 | 28 | 4.47% (4.16 - 4.81) |
| 8-9 years | 7587 | 1580 | 11 | 4.63% (4.30 - 4.98%) |
| 9-10 years | 5996 | 1554 | 13 | 4.87% (4.52 - 5.24) |
| 10-11 years | 4429 | 1495 | 8 | 5.07% (4.70 - 5.47) |
| 11-12 years | 2926 | 1618 | 0 | 5.07% (4.70 - 5.47) |
| 12-13 years | 1308 | 1293 | 0 | 5.07% (4.70 - 5.47) |
| 13-14 years | 15 | 15 | 0 | 5.07% (4.70 - 5.47) |

**Figure 1. Kaplan Meier survival curve**




Lowess curves suggested natural transitions in the odds of the outcome at volumes of 25, 50 and 110 cases/year. A two-knot model was adopted to prevent overfitting after comparison of slopes before and after the 1st knot showed no significant difference ($p = 0.806$).

All interaction terms had a p-value >0.05 and evaluation by LR tests showed the interaction terms did not improve the model's goodness of fit. Thus they were removed from the model. A model with annual surgeon volume, patient age, concomitant prolapse surgery, duration of follow-up, surgeon specialty, and hospital type with random intercepts on unique surgeon and hospital IDs was evaluated (Table 3). It showed facility type and surgeon's base specialty were not significant. LR tests showed these covariables did not improve fit. Insertion

hospital was found to contribute minimally to the outcome (2.2% of the variance) and was removed from the final model. Individual surgeon ID independent of the surgeon's annual volume contributed to 24.4% of the model's variance (95% CI 14.0–42.6) and remained a random intercept. McFadden's R2 for the final model was 0.383, indicating a satisfactory goodness of fit.

Decision was made to include patient age and duration of follow-up in the final model, despite LR tests showing they did not provide statistically significant improvements in fit, and the most parsimonious model by lowest BIC score would have excluded them. The decision was made adjust for these, as it seemed biologically plausible that both variables it would have a relationship with the outcome. The OR for duration of follow-up almost reached statistical significance, and because it inherently makes sense that those with longer follow in the dataset would have increased risk of repeat surgery, it did not seem reasonable to exclude this variable. Patient age was kept as older individuals could have decreased risk of revision due to competing risk of death or illness too severe to allow them to return to the operating room for revision years later.

For patient-related risk factors, only concomitant prolapse surgery was associated with revision surgery. The fixed-effects model common to all surgeons indicates that for those surgeons inserting 1 to 50 MUS per year, the odds of revision surgery did not change per additional case performed. In the range of 51 to 110 MUS per year, the odds of revision surgery did decline (OR = 0.99 per additional case, 95% CI 0.98–0.99, $p = 0.030$). However, after 110 cases per year, the odds of revision surgery did not further improve. For ease of interpretation, Table 4 expresses these findings in incremental units of 10 additional cases per year, and this model has been converted to the probability scale and is shown in Figure 2.

Kaplan Meier survival curves by groupings of annual surgical volume are shown in Figure 3. Log rank test was significant ($p<0.001$), indicating statistically significant differences in cumulative incidence of revision surgery favoring high volume surgeons. Shapes of these curves were similar for all groups, suggesting that the timing of revision surgery is not related to annual surgical volume. That is to say, it does not appear that cases lower volume surgeons are revised earlier than those of higher volume surgeons, and vice versa.

Two hundred and thirty individual surgeons contributed cases to the data, representing 190 gynecologists and 40 urologists. The median number of MUS per surgeon each year is shown in Table 2. Ninety-seven surgeons were considered to have performed a very low volume of MUS procedures. Of the 133 surgeons who contributed majority of cases, 104 were gynecologists and 29 were urologists. Thirty-one surgeons were considered to have performed a high volume of MUS procedures (> 50 cases per year). There was no differential loss to follow-up between low- and high-volume surgeons.

### Sensitivity Analysis

Results of the sensitivity analysis were consistent across these models (Table 5). This suggests that the relationship between annual surgeon volume and risk of revision surgery exists when data is restricted to 1-, 3-, and 5-year follow-up, and when ultra low volume physicians are excluded. This suggests the results of the final model are not driven by the outcomes of those performing extremely small number of cases, nor is it driven by the results of the early years of MUS provision in Alberta when surgeons in Alberta may have been on their "learning curve."

**Table 4. Multi-variable mixed-effects logistic regression model evaluating the relationship of patient and health system factors to the outcome of revision surgery after MUS**

| Variable | OR | 95% CI | *p* |
|---|---|---|---|
| Patient age (years) | 1.00 | 0.99–1.01 | 0.974 |
| Duration of follow-up (years) | 1.02 | 1.00–1.05 | 0.054 |
| Concomitant native tissue prolapse surgery | 1.24 | 1.04–1.48 | 0.018 |
| Facility type | | | |
| Academic hospital (reference) | | | |
| Urban hospital | 0.81 | 0.62–1.04 | 0.108 |
| Rural hospital | 0.81 | 0.58–1.12 | 0.196 |
| Surgeon | | | |
| Urologist (reference) | | | |
| Gynecologist | 0.95 | 0.69–1.30 | 0.737 |
| Surgeon's annual volume of MUS inserted | | | |
| 1–50 cases, per additional 10 cases | 1.01 | 0.94–1.10 | 0.914 |
| 51–110, per additional 10 cases | 0.91 | 0.84–0.98 | 0.024 |
| 110+ cases, per additional 10 cases | 1.01 | 0.95–1.08 | 0.794 |

**Table 5. Final mixed-effects logistic regression model**

| Variable | OR | 95% CI | *p* |
|---|---|---|---|
| Patient age (years) | 1.00 | 0.99–1.01 | 0.916 |
| Duration of follow-up (years) | 1.02 | 0.99–1.04 | 0.057 |
| Concomitant native tissue prolapse surgery | 1.23 | 1.03–1.46 | 0.019 |
| Surgeon's annual volume of MUS inserted | | | |
| 1–50 cases, per additional 10 cases | 1.01 | 0.93–1.10 | 0.791 |
| 51–110, per additional 10 cases | 0.91 | 0.85–0.99 | 0.030 |
| 110+ cases, per additional 10 cases | 1.01 | 0.95–1.07 | 0.816 |

**Figure 2. Probability of revision surgery by inserting surgeon's annual volume of midurethral sling procedures**

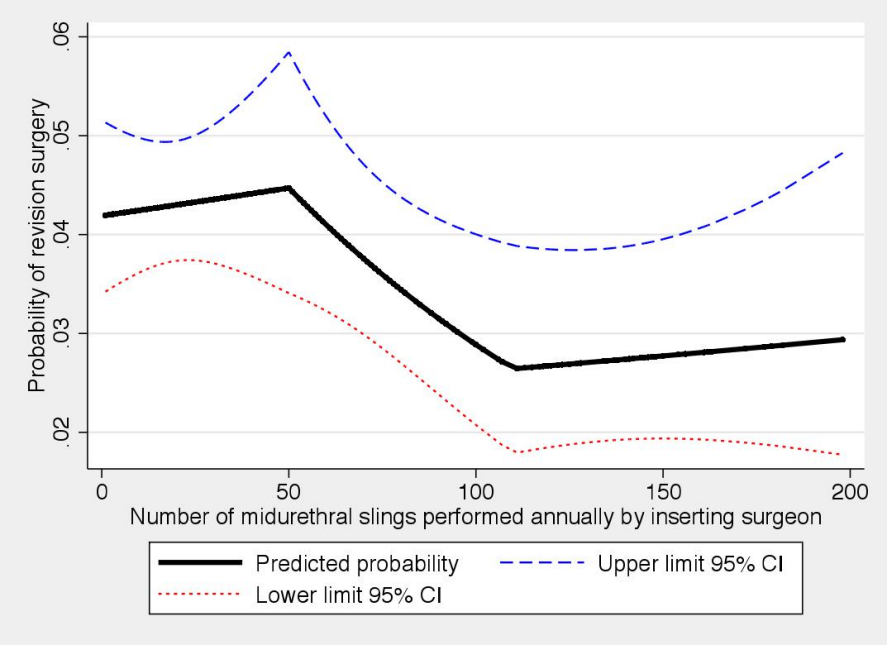



**Figure 3. Kaplan Meier survival by annual surgical volume of inserting surgeon**

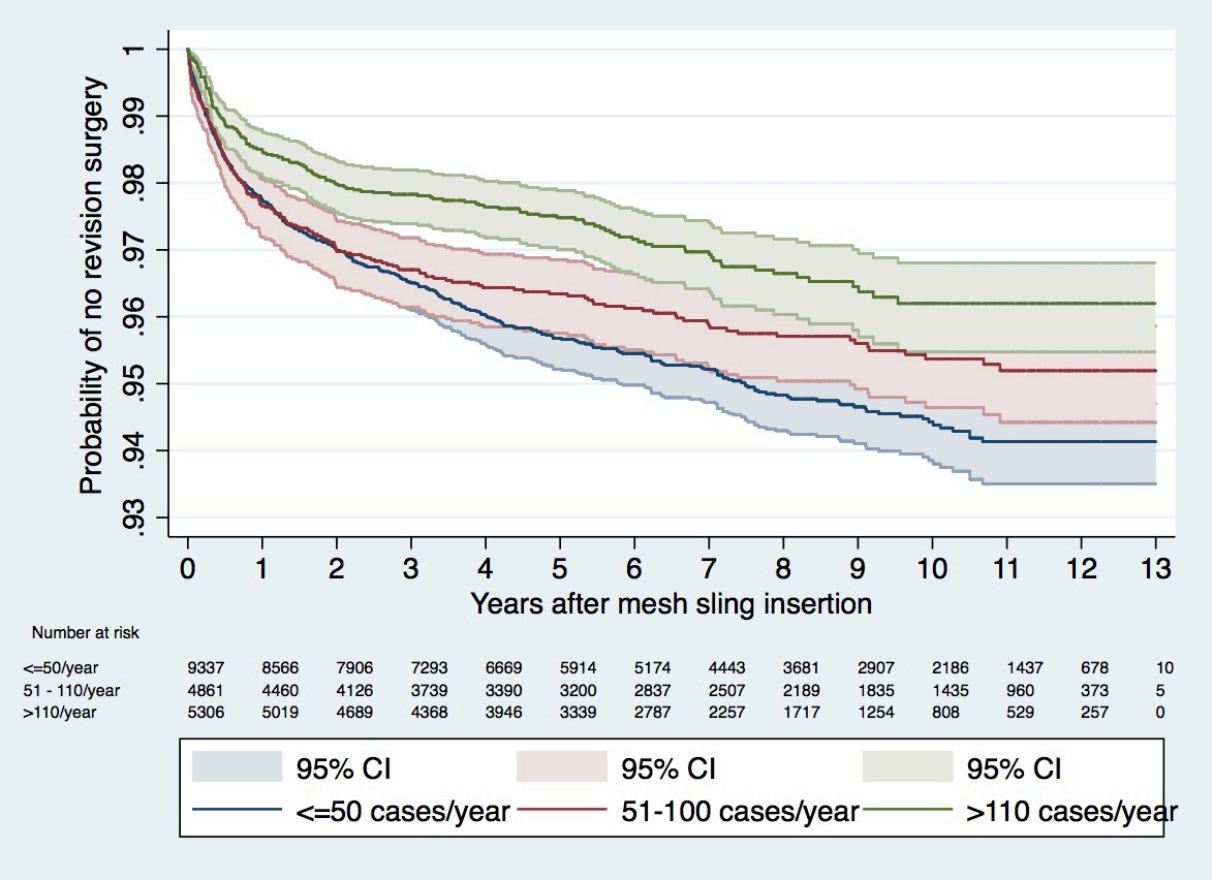


**Table 6. Sensitivity analyses at 1-, 3-, and 5-years complete follow-up**

| Variable | OR | 95% CI | *p* |
|---|---|---|---|
| **1-year follow-up** | | | |
| Duration of follow-up (years) | 1.02 | 1.00–1.05 | 0.057 |
| Concomitant native tissue prolapse surgery | 1.23 | 1.04–1.46 | 0.018 |
| Annual volume of MUS inserted | | | |
| 1–50 cases | 1.00 | 0.99–1.01 | 0.787 |
| 51–110 | 0.99 | 0.98–1.00* | 0.030 |
| 110+ cases | 1.00 | 0.99–1.01 | 0.816 |
| | | | |
| **3-year follow-up** | | | |
| Duration of follow-up (years) | 1.01 | 0.99–1.06 | 0.550 |
| Concomitant native tissue prolapse surgery | 1.24 | 1.04–1.48 | 0.018 |
| Annual volume of MUS inserted | | | |
| 1–50 cases | 1.00 | 0.99–1.01 | 0.552 |
| 51–110 | 0.99 | 0.98–1.00* | 0.047 |
| 110+ cases | 1.00 | 0.99–1.01 | 0.966 |
| | | | |
| **5-year follow-up** | | | |
| Duration of follow-up (years) | 1.04 | 1.00–1.08 | 0.064 |
| Concomitant native tissue prolapse surgery | 1.27 | 1.05–1.53 | 0.012 |
| Annual volume of MUS inserted | | | |
| 1–50 cases | 0.99 | 0.99–1.00 | 0.109 |
| 51–110 | 0.99 | 0.99–1.00* | 0.044 |
| 110+ cases | 1.00 | 1.00–1.01 | 0.108 |
| | | | |
| **Model with very low-volume surgeons removed** | | | |
| Duration of follow-up (years) | 1.00 | 0.99–1.00 | 0.062 |
| Concomitant native tissue prolapse surgery | 1.21 | 1.02–1.44 | 0.033 |
| Annual volume of MUS inserted | 0.99 | 0.98–0.99 | 0.029 |
| 1–50 cases | 1.00 | 0.99–1.01 | 0.771 |
| 51–110 | 0.99 | 0.98–0.99 | 0.029 |
| 110+ cases | 1.00 | 0.99–1.01 | 0.813 |

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

## Chapter 4: Discussion

Revision surgery occurs for a small proportion of women undergoing MUS. In the cohort under study, the 10-year revision rate was 4.87% (95% CI 4.52 - 5.24). This is comparable to results using data from the National Health Service (NHS) in the United Kingdom,[37] data from the United States,[32] and Canadian data from the province of Ontario.[33] Documenting mesh re-operation rates from a population-based perspective is important, as estimates of complications from registries such as the FDA MAUDE database are felt to be biased.[31]

This documentation of low rates of revision for MUS is important in the current medico-legal climate, given the intense worldwide media coverage of the FDA, Health Canada, and NHS warnings and class-action lawsuits from women who have experienced complications. Presentation of surgical risk is not well represented by the lay media, and online media is rife with anecdotes.[26] This has resulted in a significant amount of fear among patients considering MUS surgery. The precise rates of revision surgery produced by this study can provide a counterbalance.

When the low rates of revision surgery after MUS insertion are contrasted against the much higher rates reported for vaginal mesh procedures for POP,[56] it supports suggestions[33] that warnings related to pelvic mesh should distinguish between POP and SUI and related recommendations and device concerns.

This study's characterization of how a surgeon's annual case volume impacts risk of revision surgery suggests a non-liner relationship. In this study's 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 patients' outcomes. In the current medico-legal climate, this experience may be best obtained through additional training; this study supports the recommendations of experts and regulatory bodies that surgeons performing mesh procedures receive specialized experience and training.[32,33,57,58,59] Furthermore, it suggests outcomes could be improved by developing policies addressing surgeon risk factors.

Concomitant non-mesh surgery for POP was also associated with an increased risk of revision surgery. This finding is in agreement with other studies which reported similar magnitude of effect.[32,33,56] It has been suggested this is due to additional dissection, trauma, and changes to anatomy that occur due to additional vaginal procedures. Given the reproducibility of this finding, surgeons may want to consider separating surgeries into two stages, waiting to perform a MUS insertion until the patient has completely healed from POP surgery.

While it has been suggested that the nature of gynecologic and urologic training and practice could lead to differences in outcomes,[33,42] this study suggests no significant difference in rates of revision exist between the two specialties. This is important, as it supports that policies and credentialing standards regarding MUS procedures should be uniformly applied to each discipline.

Inpatient administrative data has previously been utilized to study the long-term risks of MUS.[32,33,37] The procedural codes utilized in this study are the same as those used by Welk et al. (2015),[33] given that the province of Ontario uses the same national Canadian coding standards as Alberta.[45] However, procedural coding in the United Kingdom (NHS)[37] and US data sources[32] differ. Despite different coding frameworks, however, the estimates of revision rates are similar. Like previous studies, the current study examined the risk of revision surgery using the cumulative incidence[33,37] and Kaplan-Meier curves.[32] Additionally, we reported non-cumulative

risk at each year post-operative to determine which windows held the greatest risk of revision. Prior work has examined risk factors for revision utilizing Cox proportional and Fine-Gray hazard models,[32,33,37] treating the outcome as survival data with competing risk. The model in the current study asks similar questions to these prior works but allows for the existence of non-linear relationships for surgeon's annual volume and a graphical depiction of the model. This allows a more detailed understanding of how risk of revision changes along a continuum of surgical volume. The study, in addition to previous works using administrative data,[32,33,37] supports the idea that the use of de-identified, patient-level data routinely collected for administrative and claims use makes the study of uncommon outcomes after MUS procedures feasible. Furthermore, the relationship that has previously been suggested between revision surgery and surgeon operative volume is robust.

One of the strengths of this study is the population-based approach and large size, which allow more precise and generalizable estimates of rates and risk factors for revision surgery than do clinical trials. Comparable rates of revision in this study and those from other health systems indicate that quality and performance of MUS 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 in this study should not be taken as absolute. This study is the first to model physician annual volume in a non-liner context, which 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. The inclusion of limited patient factors in this study (age, concomitant prolapse surgery) is a limitation of our model. This is due to the fact that medical co-morbidities (such as respiratory disease, smoking status, obesity) are not coded in NACRS if they are not the reason for admission (in these cases, indication was

surgery for SUI). Another limitation of this study is that the possible reasons that the risk of repeat surgery begins to plateau along the continuum of surgical volume cannot be explored in depth. 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 MUS procedures have a higher proportion of complex patients, such as those with both SUI and pre-existing 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 datasets. This type of measurement information bias is a known limitation of the 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 could not be distinguished in this study.

## Chapter 5: Conclusions and Next Steps

Rates of revision surgery after MUS are low (2.08% within 1 year) and comparable across healthcare systems.[23,24,28] The findings of this study suggest that a surgeon's annual operative volume is a health system risk factor that influences an individual patient's risk of undergoing revision surgery after an MUS is inserted. Factors such as hospital type and location, nor the surgeon's base specialty, appear to influence this risk. This study supports recommendations that MUS procedures are better performed by those with experience. An annual caseload of more than 50 MUS procedures performed by a surgeon is a potentially modifiable factor to improve patient outcomes.

The risk of patients needing revision surgery is similar among surgeons in the range of 1 to 50 cases per year. After this point, it begins to decline. This work implies that rates of revision surgery after MUS procedures could potentially be improved if surgeons keep their annual volume above a critical threshold.

Unlike the American model of healthcare where patients can look up how many cases a surgeon has performed,[60] surgeon metrics such as cumulative or annual operative volumes are not information that is freely available in Alberta for patients to consider when they are choosing their provider for an operative procedure. As such, a patient is unable to optimize their own care by ensuring their surgeon is a high-volume provider. Therefore, from a patient advocacy perspective, the operative volume of a surgeon should be freely available as part of the consultative process and as part of their informed decision-making. Alberta Health Services already provides wait time information for individual surgeons through their website,[61] and this piece of information could be integrated into the same or a similar program.

From an administrative standpoint, the development of practices and policies to optimize outcomes for women needing MUS insertion in Alberta should also take place. In Alberta, MUS procedures were never been restricted to subspecialty-trained surgeons or to those who have a special interest or high-volume practice. Instead, a culture of self-regulation existed. However, in the last 5 years formal and informal restriction of various pelvic procedures has begun to take place. In 2015, the Alberta Provincial Gynecologic Oncology Team issued Clinical Practice Guidelines for Alberta Health Services (AHS) which formally restricted treatment of all endometrial cancer, regardless of grade, to gynecologists with a fellowship in oncology. This was in contrast to a long history of early grade Endometrial Cancer being treated by generalist gynecologists. The change was largely brought about by the evidence suggesting that endometrial cancer cases treated by high-volume surgeons have improved long term outcomes.[62] Building upon this, in 2016 a detailed Obstetrics and Gynecology Clinical Privilege List was developed for AHS.[63] This list is reviewed annually by each Obstetrician/Gynecologist with hospital privileges in Alberta as part of the Annual Information Verification and Attestation (AIVA) and Periodic Review processes. The AIVA requires both the individual physician and their Zone Clinical Department Head to mutually agree which procedures can be performed.[64] Procedures such as pelvic lymph node dissection, intra-uterine insemination, chorionic villus sampling are listed on this document as being firmly restricted to those who have completed the appropriate fellowships. In contrast, other pelvic procedures such as those for pelvic organ prolapse and incontinence have looser, informal restrictions and are able to be credentialled to individuals deemed to have "experience satisfactory" to their own Zone Clinical Department Head (ZCDH) regardless of fellowship status.[63] No framework is provided for ZCDH judge what is satisfactory, and it is possible each ZCDH could have different standards.

Building upon the work done to develop AHS' Obstetrics and Gynecology Clinical Privilege List, possible practices and polices related to MUS insertions that could be explored for feasibility and acceptance would include 1) mandating that surgeons maintain a minimum volume for provision of ongoing privileges, 2) creating programs aimed at supplementing a low-volume surgeon's experience through additional training and mentoring so they can boost their outcomes to the level of higher-volume surgeons, 3) consolidating MUS cases within a surgical group such that a local expert within a referral catchment perform all MUS procedures, and 4) redirection of all MUS procedures to high volume surgeons in Edmonton and Calgary zones. While restrictive policies may be viewed unfavourably by lower-volume surgeons, they are in line with the position statements from relevant international organizations that suggest mesh procedures such as MUS insertions be performed only by subspecialty- and fellow-trained urogynecologists.[30,56]

The mechanisms of human judgement and decision making are complex, but many policies in healthcare are made using assumptions and idealizations of human behavior.[65] The traditionally held theories regarding human judgement and medical decision making are normative, addressing the idea of how people "should" make their decisions and expecting them to behave predictably in the face of risk and possible consequences.[66] However, work by Tversky and Kahneman has long challenged assumptions of human rationality by showing that humans respond inconsistently to escalating risk of death and disability (standard gambles).[67] Additionally, evidence suggests that patients do not make their decision solely based on numerical information (such as those related to rates of complications),[68] but rather by an intuitive "gist" based reasoning which is more unpredictable.[69] This unpredictable behavior is reflected in work examining patient opinions on regionalization of procedures. For example,

procedural regionalization is known to result in minimal increase in travel time for urban dwellers, but most significantly impacts those living in rural areas.[70] Research exploring the preferences for location of care for individuals living >1 hour driving from a tertiary care centre have found contrasting results. One study of aortic aneurism repair in Ontario found that even if outcomes were presented as the same between a local surgical site vs. tertiary care centres, half of individuals would still prefer to travel to a tertiary high-volume centre. The great majority (91%) were unwilling to accept any degree of elevated mortality if they have surgery performed locally.[71] In contrast, a study of American veterans undergoing pancreatic resection found that when outcomes were presented as the same between home (relatively low volume hospitals) and tertiary centres, that all patients preferred local care close to home. Preferences began to diverge when risk associated with local surgery was presented as sequentially elevated relative to the risk at a high-volume centre.[72] But even when operative mortality risk was presented as 18% in local volume centres (vs 3% in a tertiary centre), 18% of individuals awaiting a pancreatic resection indicated they would prefer to have surgery in their home centre. Examples such as these papers use normative, top-down theories of decision making that assume the ideals of how individuals think.[73]

Qualitative research examining Albertan women's preferences for location of care when considering MUS procedures would be valuable, because the results of both these studies can not be directly extrapolated to MUS procedures. Reasons for this include the fact that both studies included predominantly men (78% & 91%) who were significantly older (median age 65) than the average woman undergoing a MUS procedure in Alberta. Additionally, only biologically female individuals undergo MUS procedures, and the female gender roles associated with care giving, domestic labor, sexual function, and body image could influence women's perception of

risk and their preferences in ways that differ from men. Furthermore, individuals may have a different appetite to accept a finite risk such mortality, compared to the risk of complications that could endure for a lifetime (e.g., chronic pain) after MUS procedures. For this reason, examination of decision making in Alberta's population should not be performed utilizing normative theories, but rather be examined through a bottom-up, descriptive context describing how women think in the real world.[73] This information could then be used to frame evidence such as the information of this study for decision making aids, to help facilitate decision making about where and with whom to receive a surgical procedure such as MUS.[73]

The first step in crafting procedures and policies would be presentation of this project's findings at a provincial stakeholder meeting including managers and administrators from all five zones of Alberta Health Services, zone department heads from departments of obstetrics and gynecology and departments of surgery, gynecologic and urologic surgeons, and patient advocates. The discussion at such a meeting could explore the above and may generate new possible options. The viewpoints of various stakeholders would guide the development of practices and policies for MUS procedures in Alberta, taking into account the feasibility of implementing them and the impact on patients.

Changing medical behaviour is not easy, although there is evidence that behavioural change interventions that are evidence based and informed by theory are more effective.[74,75] As such, the theoretical domains framework (TDF) could be used to assess for potential barriers to implementation as well as form the basis of intervention development.[76] The TDF identifies 14 domains that act as barriers or enablers to the implementation of evidence-based guidelines: Knowledge; Skills; Social/Professional Role and Identity; Beliefs about Capabilities; Optimism; Beliefs about Consequences; Reinforcement; Intentions; Goals; Memory, Attention, and

Decision Processes; Environmental Context and Resources; Social Influences; Emotions; and Behavioural Regulation. To increase the likelihood that practices and policies are embraced by relevant stakeholders, engaging an expert in knowledge translation and the TDF framework for future stakeholder meetings would be beneficial.

Future research could include repeating this study using national Canadian administrative data to examine if the effect of surgeon's annual volume on revision surgery is consistent across all provinces and territories. Combining data from multiple health systems would also allow examination of the relationship between annual surgical volume and outcomes at a more granular level. This would allow greater confidence in saying at what threshold improved rates of revision surgery begin to occur, and it is possible that the recommended minimum number of procedures per year could be changed after this analysis. Given that a national study would include more high-volume surgeons (> 110 cases per year), it would also allow re-examination to see if a plateau in risk still occurs in this range. Additionally, this model could be applied to other health outcomes such as emergency room visits and re-admission to hospital within 30 days of surgery.

Additionally, the data used in this study could be examined through additional lenses related to health services research. From an economic perspective, the cost of revision surgery could be determined. After this, future work could model what the projected cost savings would be if MUS procedures were restricted to high-volume surgeons, thereby avoiding a proportion of revision cases.

Furthermore, the Health Canada warning[16] regarding use of mesh occurred in the middle of the time window captured by our cohort. This creates a sort of natural experiment where future work could evaluate if the Health Canada warning resulted in changes to how MUS is provided in Alberta. Comparison of case characteristics (Table 1) suggests that differences do

exist across the years of the cohort. These may reflect small changes that we are able to detect due to large sample size but have no basis in practice change. But the differences may also hint that surgeons began to change their MUS practice over time. Therefore, an evaluation using interrupted time series could explore whether differences exist pre and post warning period volume of MUS cases performed, number of surgical providers, and which hospitals offer the procedures in Alberta.

In summary, nearly two decades after their introduction, MUS procedures are the most rigorously studied incontinence procedure in the literature. At present, no other surgery, including those developed subsequent to it, offer equivalent rates of patient-reported and objective cure. As such, they remain the gold standard for surgical cure of SUI, a common urologic condition. Given the aging and growing population in first world countries, the number of women who will consider this procedure in their lifetime is enormous. It is critical to optimize all factors that may increase risk of revision surgery, both to reduce the economic burden of additional operations and to avoid unnecessary difficulties for these patients.

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## Appendix

**Table A1. Individual CCI codes representing index MUS 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 (e.g. 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 (e.g. tension free vaginal tape (TVT), Monarc, SPARC) | April 2009–present |
| 1.PL.74.AL-FF | 2,858 | Fixation, bladder neck combined percutaneous and vaginal approach using tension free vaginal tape technique (TVT) | 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 (e.g. laparotomy, pubovaginal sling) | April 2006–present |
| 1.PL.74.DA-XX-N | 269 | Fixation, bladder neck endoscopic (laparoscopic) approach using synthetic material (e.g. 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 tension free vaginal tape technique (TVT) | April 2002–March 2006 |

Note: Total number exceeds 19,511 as MUS cases could have more than one CCI code assigned to them.

**Table A2. Individual CCI 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 (tension free vaginal tape 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) (tension free vaginal tape 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 [tension free vaginal tape] using vaginal approach | April 2006–present |
| 1.PL.55.LA-XX-N | 72 | Removal of device, bladder neck of synthetic urethral sling [tension free vaginal tape] 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 (i.e. urethrolysis) | April 2002–present |
| 1.PQ.86.^^ | 12 | Closure of fistula, urethra, by any approach | April 2002–present |

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