

Two Intraoperative Techniques for Midurethral Sling Tensioning

A Randomized Controlled Trial

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OBJECTIVE: To evaluate whether the use of a Mayo Scissor as a suburethral spacer compared with a Babcock clamp holding a loop of tape under the urethra results in different rates of abnormal bladder outcomes 12 months after retropubic midurethral sling surgery.

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Each author has confirmed compliance with the journal's requirements for authorship.

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Erin Brennand has received grant funding from Boston Scientific. Sara Houlihan is a paid speaker for Astellas and Boston Scientific. Dobrochna Globerman has been a speaker for Pfizer. Colin Birch and Darren Lazare have been clinical proctors for Boston Scientific. Dr. Kevin Carlson has been on an Astellas advisory board and received payment for attending a consultancy meeting with Boston Scientific. The other authors did not report any potential conflicts of interest.

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METHODS: The MUST (Mid-Urethral Sling Tensioning) trial was a block-randomized, double-blind, multicenter clinical trial that allocated women to have their retropubic midurethral slings tensioned by Scissor or Babcock technique. The primary outcome (abnormal bladder) was a composite of persistent stress urinary incontinence (SUI), overactive bladder, and urinary retention. Secondary outcomes included outcomes of the composite, postoperative catheterization, incontinence-related questionnaires, repeat incontinence treatment, and uroflowmetry. Sample size of 159 in each arm (N=318) was planned for a superiority trial, hypothesizing a 10% difference in primary outcome.

RESULTS: From September 2015 to December 2017, 506 women were screened and 318 were randomized. Baseline characteristics were similar in each arm. At 12 months, 253 (79.6%) women provided information on primary outcome: 40 of 128 (31.3%) patients with midurethral slings tensioned by Scissor experienced abnormal bladder, compared with 23 of 125 (18.4%) of those with midurethral slings tensioned by Babcock (P=.018, relative difference 12.9%). Secondary analyses favored Babcock for median duration of catheterization and the proportions of women experiencing urinary retention requiring sling lysis. Uroflowmetry parameters suggest the Scissor technique is more restrictive. Rates of mesh erosion were lower for the Scissor arm. No differences occurred in proportions of women experiencing patient reported persistent SUI after surgery.

CONCLUSION: Abnormal bladder outcomes were 12.9% less frequent for women with midurethral slings tensioned by Babcock. Both techniques provided a comparable patient reported cure for SUI at 12 months. Women with midurethral slings tensioned by Scissors experienced more intervention for obstruction, whereas those with midurethral slings tensioned by Babcock experienced higher rates of mesh erosion. This informa-

tion about how the postoperative courses differ allows surgeons to better counsel patients preoperatively or tailor their choice of technique.

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Midurethral slings are the most commonly performed surgery for stress urinary incontinence (SUI). Although midurethral sling procedures provide high rates of cure for SUI, they are associated with risks of de novo overactive bladder, urinary retention and mesh erosion. Rates of reoperation after a midurethral sling are 1.4–2.2% at 1 year.^{1,2} Evidence suggests that patient-level factors, such as body mass index (BMI, calculated as weight in kilograms divided by height in meters squared) and need for concomitant prolapse surgery,^{1,3,4} and health system factors, such as a surgeon's annual operative volume,^{1,5,6} influence outcomes. However, very little evidence exists that examines how the intraoperative technique used to determine the amount of space between the midurethral sling and the urethra, also known as setting the mesh tension,⁷ affects surgical outcomes.^{8,9} Furthermore, many of the randomized controlled trials (RCTs) reporting outcomes after midurethral sling procedures do not elaborate on what tensioning mechanism was used, despite existence of many techniques.^{10,11}

We designed the MUST (Mid-Urethral Sling Tensioning) RCT to compare two techniques for setting the tension of retropubic midurethral slings (also referred to as tension-free vaginal tapes): 1) a Mayo Scissor between the tape and urethra acting as a “spacer” or 2) a Babcock clamp on a measured loop of the tape. These techniques were selected because they represent the most commonly employed tensioning method (Scissor) and a less commonly known, but highly reproducible technique (Babcock).⁸ The objective of this RCT was to compare whether differences exist between the techniques in rates of common suboptimal postoperative outcomes, such as de novo overactive bladder, urinary retention requiring intervention, and persistent SUI. These defined our primary composite outcome (“abnormal bladder outcome”), a similar composite outcome similar to other RCTs.^{10,11}

ROLE OF THE FUNDING SOURCE

As an investigator-initiated, industry-sponsored trial, the authors had full access to the study's data. Study

protocol and analytic plan were written by the study authors. The authors take responsibility for the presentation and publication of the research findings, have been fully involved at all stages of publication and presentation development, and are willing to take public responsibility for all aspects of the work. All individuals included as authors and contributors who made substantial intellectual contributions to the research, data analysis, and publication or presentation development are listed appropriately. The sponsor had no role in the design, execution, analysis, or reporting. The sponsor had no access to data in record or aggregate form. Funding is fully disclosed. The authors' personal interests, financial or nonfinancial, relating to this research and its publication have been disclosed.

METHODS

This randomized, double-blinded, multicenter clinical trial was conducted by seven surgeons (fellowship-trained urogynecologists and urologists) in three tertiary care hospitals (Calgary, Alberta; Edmonton, Alberta; Vancouver, British Columbia) and one academic community hospital (Calgary, Alberta) in Canada. The study was approved by the University of Calgary Conjoint Health Research Ethics Board (Ethics ID 150455). The study protocol was registered at ClinicalTrials.gov (NCT02480231) and published in an open-access journal for transparency.⁸

Women were eligible for inclusion if they had SUI demonstrated by a cough stress test during an office visit or urodynamic evaluation. Participants had elected to undergo a midurethral sling for management of their SUI independent of the trial. Women were excluded if they had previous incontinence surgery; symptoms of severe urinary urgency (ie, urge-related urine loss, two or more episodes of nocturia per night, and detrusor overactivity on urodynamics); preexisting clinical signs of urinary retention, such as more than 100 mL postvoid residual; expressed plans for future childbearing; preexisting neurologic disease such as Alzheimer's, Parkinson's disease, or multiple sclerosis; were unable to communicate in English; or indicated they would be unavailable for 12-month follow-up. Patients who agreed to join the study provided written informed consent with study personnel other than their primary surgeon. This was performed after the routine surgical paperwork was completed. On enrollment, participants completed a package of questionnaires, including demographic and medical information, the Incontinence Severity Index (a two-item tool to assess frequency and amount of leakage), the International

Consultation on Incontinence Questionnaire Female Lower Urinary Tract Symptoms Long Form Module (an 18-item tool for evaluating female lower urinary tract symptoms),¹² the Urogenital Distress Inventory (a six-item measure of urogenital distress), and the Incontinence Impact Questionnaire (a seven-item measure of incontinence effect).¹³

Participants were randomly allocated to have their retropubic midurethral sling tensioned either by using a Mayo Scissor as a spacer or by the use of a Babcock clamp to create a 1.4-cm loop held by the instrument. A detailed description of both techniques has been published previously⁸ and is shown in Figures 1–3. Randomization list was generated by a statistician within the Department of Obstetrics & Gynecology, University of Calgary using the ralloc procedure in STATA 15.1, which creates permuted block randomization with block sizes varying from one to eight. Stratification by surgeon and planned concomitant prolapse surgery was done. Neither the surgical team nor the patient were told of the allocation group, which was conveyed directly to the attending surgeon by the study coordinator within 24 hours of the surgical procedure.

All surgeons were experienced with the placement of retropubic midurethral slings, and all procedures were performed with the Boston Scientific Advantage Fit device. Intraoperative cystoscopy was

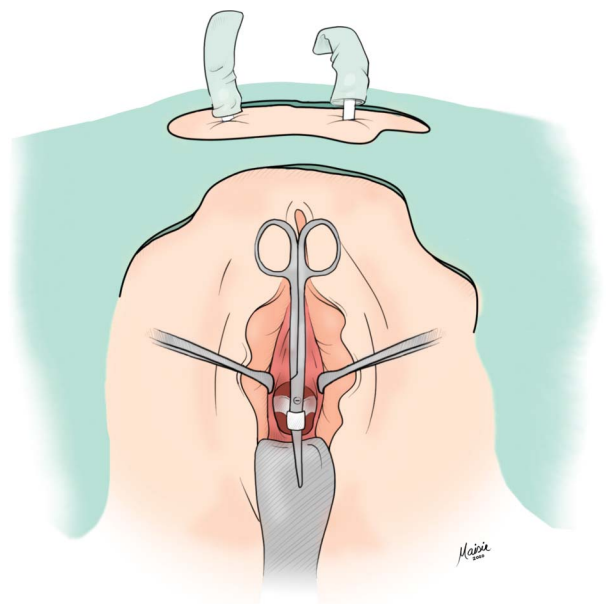


Fig. 1. Setting the midurethral sling tension by Mayo Scissor as a spacer. Illustration created by Maisie Mattatall. Used with permission.

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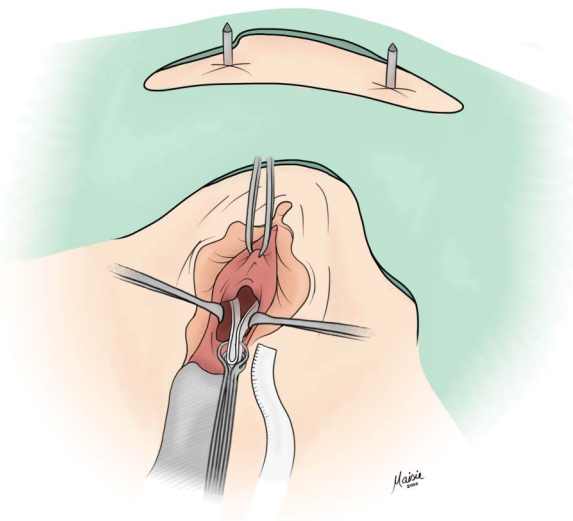


Fig. 2. Measurement of a 1.4-cm loop held by Babcock clamp. Illustration created by Maisie Mattatall. Used with permission.

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performed for all procedures. Procedures with concomitant prolapse surgery were planned admissions. Isolated midurethral sling operations were planned as outpatient procedures. Surgical details were recorded by the attending surgeon on study forms or extracted

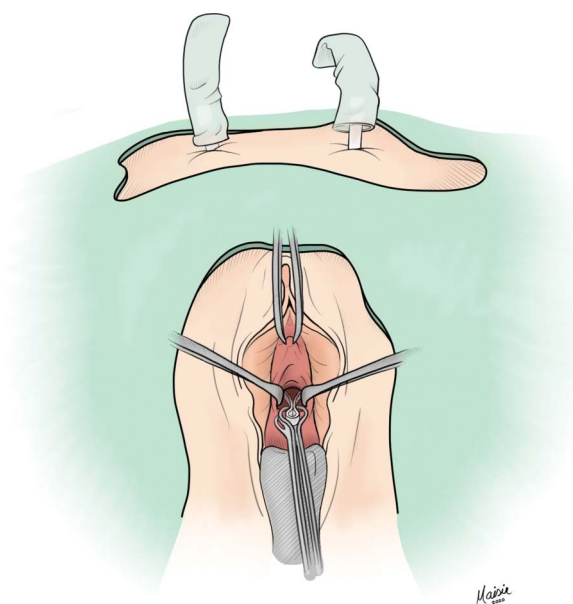


Fig. 3. Holding a fixed loop of tape within Babcock clamp while tensioning midurethral sling. Illustration created by Maisie Mattatall. Used with permission.

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from patients' charts, which then was subsequently verified by the surgeon.

At the 6-week in-person visit, patients were asked to recall any problems that were managed by a health professional other than their surgeon. Each clinic and hospital chart was reviewed to capture information about possible complications from the surgeon's notes. Participants were invited to attend a 12-month postoperative follow-up appointment with a blinded outcome assessor, a urogynecologist who did not perform their surgery. During this visit, participants completed the same standardized questionnaires that were administered at enrollment, in addition to standardized physical examination of operative incisions and speculum along with digital examinations to palpate and visualize for tape erosion and pain. Women were asked to attend their visit with a comfortably full bladder. For those who had voided before examination, a retrograde bladder fill with 300 mL of sterile water was performed. If the patient expressed severe urge, smaller volumes for filling were allowed. Objective evidence of persistent SUI was obtained using a cough stress test in supine position, being instructed to cough once forcefully. If no leakage was observed, women were instructed to cough three additional times. If leakage was not seen in supine lithotomy position, women were reexamined standing. The requirements of this cough stress test are in keeping with the uniform Cough Stress Test endorsed by the International Continence Society.¹⁴ A standardized pad test was also conducted with women undertaking the physical activities recommended by the International Continence Society while wearing preweighed pads.¹⁵ If the cough stress test was negative and the increase in pad weight over the test period was less than 1 g, women were considered objectively "cured."^{11,16,17} Uroflowmetry test and measurement of the postvoid residual were performed at the end of their 12-month postoperative visit to assess voiding dysfunction. If clinical concerns were identified during any portion of this visit, care was initiated by the study surgeon and then transferred back to the attending surgeon. After the study visit, the allocation group was revealed to women, if they requested this information.

Study data were collected and organized by an independent research nurse and administrator. Women who were unable to attend the clinical study visit were asked to complete the same questionnaires from enrollment. The subjective definition of patient-reported cure was a score of less than 2 on question three of the Urogenital Distress Inventory questionnaire ("Do you experience and, if so, how much are you bothered by urine leakage related to physical

activity? Walking, running, laughing, sneezing, coughing. Not at all=0, A little bit=1, Moderately=2, Greatly=3"). After all the details of the study were entered into the database (ie, 3 months after the 12-month postoperative visit), the operative record was reviewed to ensure that the group allocation was followed as per randomization.

The primary outcome was the presence or absence of abnormal postoperative bladder function, which was a composite measure composed of one or more of the following at the 12-month postoperative follow-up appointment: 1) significantly bothersome SUI or overactive bladder symptoms after surgery measured by a score of 2 or higher on questions 1, 2, and 3 of the Urogenital Distress Inventory questionnaire; 2) a positive cough stress test; 3) re-treatment for SUI (ie, repeat surgery or pessary use); or 4) postoperative urinary retention (ie, presence of self-catheterization at 6 weeks or more postoperatively or therapeutic intervention for retention, such as surgical sling release, physiotherapy, or neuromodulation in the 12-month interval). This composite measure, "abnormal bladder outcome" was chosen as it gives weight to suboptimal outcomes, such as persistent SUI, de novo overactive bladder and postoperative urinary retention. Similar composite outcome measures have been used in the past.^{10,11}

The secondary outcomes at the 12-month postoperative follow-up appointment included: 1) standardized questionnaire scores (Incontinence Severity Index, International Consultation on Incontinence Questionnaire Female Lower Urinary Tract Symptoms Long Form Module, Urogenital Distress Inventory, and Incontinence Impact Questionnaire), 2) standardized 1-hour International Continence Society pad test values, 3) uroflowmetry and postvoid residual parameters, and 4) presence of erosion on vaginal examination. Additional secondary outcomes were: 5) rates of discharge from hospital with ongoing need for catheterization, 6) duration of self-catheterization, and 7) operative details such as length of surgery and complications.

Based on the previous trials that used similar composite outcome measures,^{10,11} the estimated rate for bothersome postoperative SUI was 5.3%, 6.3% for bothersome postoperative overactive bladder, 1.1% for a surgical revision rate for urinary retention, and 4.7% for a retention rate at 6 weeks postoperatively or longer. These provided an additive prevalence for our primary composite outcome of 17.4%. However, we expected overlap within groups (eg, women with surgical revision for retention also having recurrent SUI), and so the conservative estimate of prevalence of our

primary composite outcome was 15% for the commonly performed Scissor spacer technique.⁸ Planning for a superiority trial design, 276 patients (138 per arm) were required to have 80% power to detect a 10% difference for the primary composite outcome between groups with a 95% CI ($\alpha=0.05$). A 10% difference was chosen by the study group, because this degree of improvement in the primary composite outcome would be required for surgeons to change their technique in favor of the more complex Babcock method.¹¹ Assuming 15% loss to follow-up,¹¹ the total enrollment goal increased to 318 women (159 per arm).

Intention-to-treat analyses were undertaken. After recruitment of a total of 159 women, a planned interim analysis on urinary retention rates 6 weeks postoperatively or longer was conducted. At this halfway point into the recruitment, we were powered to detect a 4-fold increase in urinary retention, which was a predetermined threshold as a reason to halt recruitment of study participants.

Access was used for data entry and management, and statistical analyses were conducted using STATA 15.1. Data discrepancies were identified through visual verification of records, range, and logic checks. All participants flagged as having experienced a complication had their records reviewed a second time by the primary investigator for confirmation. Descriptive statistics were calculated for the baseline data. The primary analysis compared the proportion of patients who experienced an “abnormal bladder outcome” at 12-month postoperative follow-up between the two groups using a χ^2 test. Fisher exact or χ^2 tests were used to compare the differences in the proportion of secondary outcomes for the two groups. Differences in the median time and questionnaire scores were compared using the Mann-Whitney U test. $P<.05$ indicated statistical significance. Complete case analysis was conducted. Results were reported according to the CONSORT (Consolidated Standards of Reporting Trials) statement extension for pragmatic trials.¹⁸

RESULTS

The study recruited 318 women from September 2015 to December 2017 (Fig. 4). Follow-up appointments were completed by December 2018. No statistically significant difference in urinary retention was detected at the mid-point of recruitment ($n=159$). Of the 318 women, 159 were randomly allocated to Scissor, and 159 were randomly allocated to the Babcock group. A total of 290 (91.2%) women provided follow-up data at the 12-month postoperative follow-up appointment.

Of these, 253 attended the follow-up appointment, completed questionnaires (79.6%) and were included in the primary outcome analysis. An additional 33 women completed questionnaires only (10.4%), and four completed the study visit but declined to complete the questionnaires (1.3%). For patients who were lost to study follow-up, but still were active patients of their surgeon at 12 months, a chart review was performed to abstract information relevant to study outcomes ($n=16$). This partial follow-up information was used for secondary analyses.

Baseline demographic and clinical characteristics of women allocated to the Scissor and Babcock group ($N=318$) are presented (Table 1). No statistical differences existed in the demographic and clinical characteristics between the two groups. For all women, surgery was performed as per randomization. Comparison of baseline characteristics was performed for those who provided a 12-month follow-up and those women who were lost to follow-up. The only statistically different characteristic was BMI, with those who did not provide follow-up having a higher BMI (30.7, 95% CI 28.9–32.5 vs 28.7 95% CI 28.0–29.4, $P=.017$). Table 2 presents operative information. The mean duration (SD) of operation in minutes was similar for women in the Scissor (32.9 ± 35.3) and Babcock (35.8 ± 35.6) groups ($P=.524$). Details regarding operative length was compared for only isolated midurethral slings. Of those women who experienced intraoperative surgical complications unrelated to the study protocol ($n=13$), five (38.5%) experienced a bladder perforation and eight (61.5%) experienced estimated blood loss of more than 200 mL. Proportions of women discharged home without need for catheterization were higher for those who had their midurethral sling tension set by Babcock in the groups undergoing isolated midurethral slings (difference 24.0%, 95% CI 8–40%) and those also undergoing concomitant prolapse surgery (difference 24.7% 95% CI 1–50%).

Fewer women who had their midurethral sling tensioned by Babcock experienced an “abnormal bladder outcome” at 12 months (Table 3). There were lower rates of urinary retention in the Babcock group and higher proportion of women with a positive cough stress test in the “Scissor” group (Table 3). Because the positive cough stress findings in the Scissor group could be the result of higher proportions of women undergoing sling lysis for urinary retention, we performed a sensitivity analysis excluding individuals who underwent sling lysis. The finding remained significant (Scissor: 14.84%; Babcock: 7.14%; $P=.050$). Of the six women who underwent

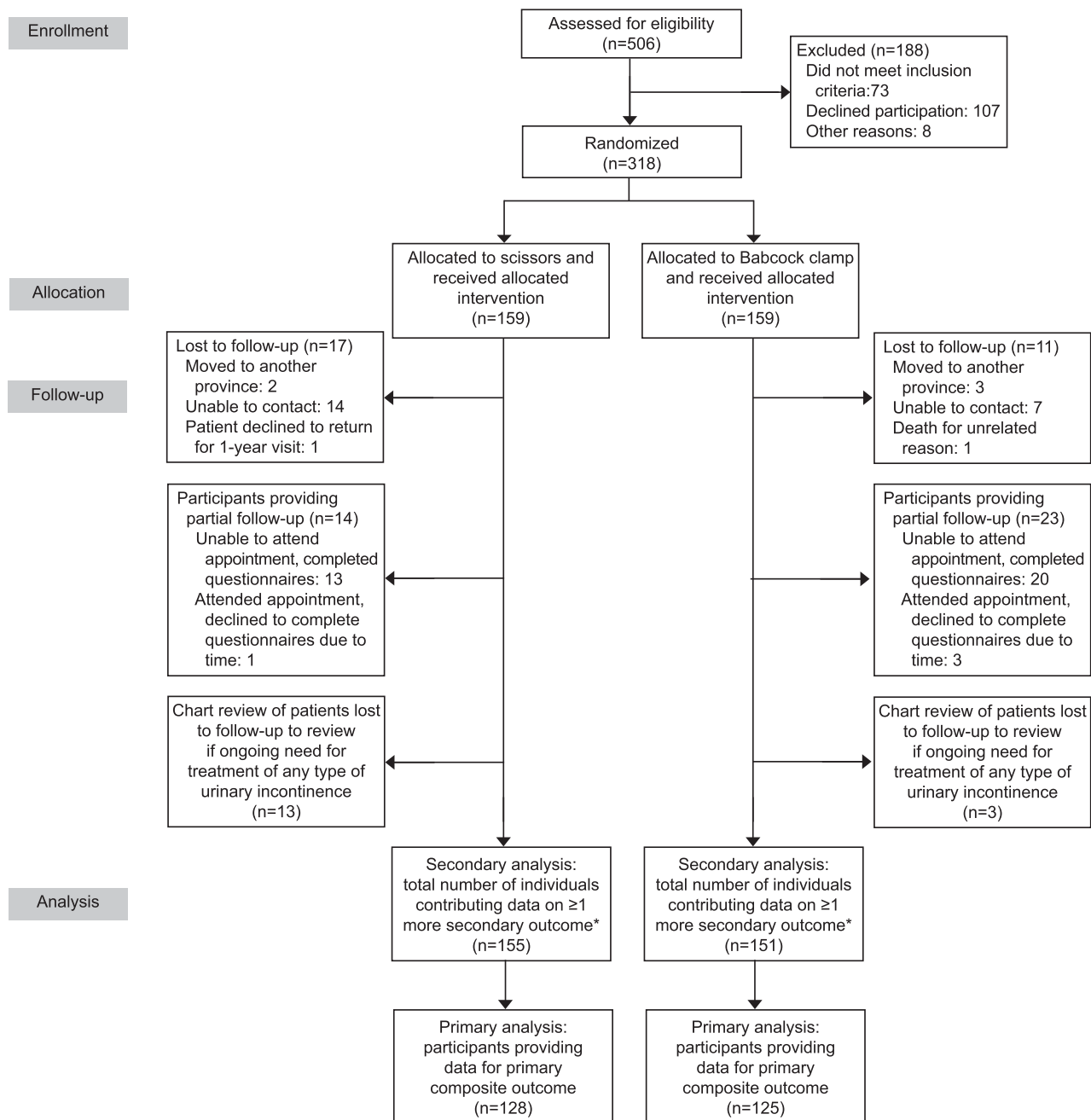


Fig. 4. CONSORT (Consolidated Standards of Reporting Trials) flow diagram. *Number of individuals for each outcome varies owing to completeness of follow-up with or without review of the medical chart.

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retreatment for SUI during the study window, two had a positive cough stress test on their 12-month follow-up examinations. Exclusion of individuals who underwent sling lysis or retreatment of SUI resulted in the difference in positive cough stress test to no longer be statistically significant (Scissor: 13.5%; Babcock: 6.9%, $P=.086$).

The five women who attended their 12-month follow-up appointments with an empty bladder required a retrofill with a mean instillation volume of 301 mL (95% CI 293–310 mL). The remaining women attended with a self-reported comfortably full bladder. The mean volume by bladder scan in this group was 408 mL (95% CI 382–435 mL). Women

Table 1. Patient Characteristics at Baseline Enrollment

Characteristic	Scissor Tensioning (n=159)	Babcock Tensioning (n=159)	P
Age (y)	51.8±12.0	50.9±11.3	.494*
BMI (kg/m ²)	29.4±6.2	28.6±5.6	.228*
Concomitant prolapse surgery			.897 [†]
Yes	39 (24.5)	40 (25.2)	
Ethnic group			.750 [†]
White	145 (91.2)	141 (88.7)	
Asian	5 (3.2)	5 (3.2)	
Black	1 (0.6)	1 (0.6)	
First Nation/Indigenous	1 (0.6)	4 (2.5)	
Other	7 (4.4)	8 (5.0)	
Smoking status			.927 [†]
Current	21 (13.4)	23 (14.7)	
Past	43 (27.4)	44 (28.0)	
Never	93 (59.2)	90 (57.3)	
Obstetric history			
Nulliparous	5 (3.1)	5 (3.1)	
Parity	2 (2–3)	2 (2–3)	.820 [‡]
No. of vaginal deliveries	2 (2–3)	2 (2–3)	.599 [‡]
Menopausal status			1.000 [†]
Premenopause	85 (56.3)	84 (56.4)	
Current HT use	11 (9.7)	17 (14.9)	.226 [†]
Questionnaire scores			
ISI	8 (4.8)	8 (6.9)	.057 [‡]
UDI-6	41.7 (29.2–50)	37.5 (25–50)	.165 [‡]
IIQ-7	47.6 (28.5–66.6)	42.8 (28.5–66.6)	.540 [‡]
ICIQ-FLUTS LF	22 (18–28)	21 (17–28)	.621 [‡]
SUI symptoms in 7 d before enrollment			.691 [†]
No or yes, but no problem	5 (3.2)	6 (3.8)	
Yes, small problem	39 (24.5)	45 (28.3)	
Yes, big problem	115 (72.3)	108 (67.9)	
UUI symptoms in the 7 d before enrollment			.681 [†]
No or yes, but no problem	61 (38.6)	59 (37.4)	
Yes, small problem	45 (28.5)	40 (25.3)	
Yes, big problem	52 (32.9)	59 (37.3)	
Nighttime waking to void in the 7 d before enrollment			.697 [†]
No or yes, but no problem	69 (43.4)	70 (44.3)	
Yes, small problem	56 (35.2)	60 (38.0)	
Yes, big problem	34 (21.4)	28 (17.7)	
Uroflow parameters			
Peak flow rate (mL/s)	27.7±11.9	27.5±11.7	.881*
Smooth, unobstructed flow pattern	133/133 (100)	148/148 (100)	1.000 [‡]
Postvoid residual (mL)	25.5±42.1	27.8±53.3	.683*
Self-reported constipation			.196 [†]
Yes	22 (14.1)	30 (19.6)	

BMI, body mass index; HT, hormone therapy; ISI, Incontinence Severity Index; UDI-6, Urinary Distress Index; IIQ-7, Incontinence Impact Questionnaire; ICIQ-FLUTS LF, International Consultation on Incontinence Questionnaire Female Lower Urinary Tract Symptoms Long Form Module; SUI, stress urinary incontinence; UUI, urgency urinary incontinence.

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

* Two-independent-samples *t* test.

[†] Pearson χ^2 test.

[‡] Wilcoxon-Mann-Whitney test.

in the Scissor group had a lower volume in their bladder during cough stress test (Scissor: 375 mL; Babcock: 432 mL, $P=.033$). Despite women in the Scissor group having less urine in their bladders, the

proportion of women demonstrating positive cough stress test was higher in the Scissor group.

For secondary outcomes, no differences existed between the groups in the four standardized

Table 2. Operative Details for Patients With Retropubic Midurethral Sling Procedures Tensioned by Scissor and Babcock

Operative Details	Scissor Tensioning (n=159)	Babcock Tensioning (n=159)	P	Difference (95% CI)*
Anesthetic			.527*	
General	104 (71.7)	114 (76.0)		
Sedation	30 (20.7)	29 (19.3)		
Spinal	11 (7.6)	7 (4.7)		
Complications				
Yes	7 (5.4%)	6 (4.5)	.279*	0.9% (-0.06 to 0.04)
Operative time for isolated midurethral sling (min)	32.9±35.3	35.8±35.6	.524 [†]	-2.9 (-6.04 to 11.82)
Catheterization at discharge				
Midurethral sling only	n=112	n=115		
None	54 (48.2)	83 (72.2)	<.001*	24.0% (0.08-0.40)
Self-catheterization	48 (42.9)	23 (20.0)		22.9% (0.01-0.44)
Indwelling	10 (8.9)	9 (7.8)		1.1% (-0.24 to 0.26)
Midurethral sling plus POP surgery	n=42	n=39		
None	23 (54.8)	31 (79.5)	.027 [‡]	24.7% (0.01-0.50)
Self-catheterization	15 (35.7)	8 (20.5)		15.2% (-0.22 to 0.52)
Indwelling	4 (9.5)	0		—
Duration of catheterization after surgery (d)	4 (0-9)	2 (0-6)		
	4 (2-7)	2 (1.5-5)	.027 [§]	-2 (-4.18 to 0.18)

POP, pelvic organ prolapse.

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

* Pearson χ^2 test.

[†] Two-independent-samples *t* test.

[‡] Fisher exact test.

[§] Wilcoxon-Mann-Whitney test.

questionnaire scores at 12 months (Table 4). Women in the Babcock group had a higher mesh erosion rate, lower rates of new overactive bladder medication use, faster mean urine flow rates, and lower proportions of uroflowmetry patterns suggesting obstructed voiding (Table 4).

DISCUSSION

Our multicenter RCT compared the rates of abnormal bladder function at 12 months for two different techniques to set the tension of retropubic midurethral sling procedures. We found that fewer women in the Babcock group experienced abnormal bladder function. Women in both groups experienced high rates of objective and subjective cure, as shown by similar pad testing and standardized questionnaire scores. Differences did exist for clinical parameters, such as slightly higher vaginal mesh erosion rate for Babcock technique and uroflowmetry parameters suggestive of subtle urinary obstruction were more common for women with midurethral slings tensioned by Scissor.

The strength of this study was our multicentered randomized double-blinded study design. The retropubic midurethral sling device was the same for all

participants, removing a source of variability. Additionally, all surgeons were fellowship-trained with high-volume surgical practices.^{1,2} One limitation is that, although the authors attempted to standardize the Scissor technique for all participating surgeons,⁸ we expect there was inherent variation both within an individual surgeon and between study surgeons given that subtle differences in the tension of the sling against the Mayo Scissor cannot be measured. As such, the authors' experience is that the Scissor technique is less reproducible than the Babcock. In counterpoint, this reflects the real-world variability that exists with this method of sling tensioning by Scissor spacer.

The selection of patients, their baseline characteristics, the setting of a trial including the selection of participating centers and clinicians are known to affect the external validity of a trial.¹⁹ Our participants were mostly white nonsmokers between the ages of 40-65 years with an overweight habitus. Baseline characteristics of our participants are similar to those described of all women undergoing midurethral sling procedures in Alberta,¹ suggesting minimal recruitment bias. Generalizability and external validity of the trial

Table 3. Primary Outcome Composite Measure and Each Component at 12-Month Follow-up

Primary Composite Outcome	Scissor Tensioning	Babcock Tensioning	P	Difference (%) (95% CI)
No abnormal bladder function	88/128 (68.7)	102/125 (81.6)	.018*	12.9 (0.02–0.23)
Abnormal bladder function (composite) [†]	40/128 (31.3)	23/125 (18.4)		
Components of the primary outcome [‡]				
Bothersome SUI symptoms	29/139 (20.3)	30/138 (21.7)	.764*	1.5 (–0.08 to 0.11)
Bothersome OAB symptoms	22/136 (16.2)	12/141 (8.5)	.073*	7.7 (–0.00 to 0.15)
Positive cough stress test	21/129 (14.3)	9/128 (7.0)	.048*	–7.7 (–0.15 to 0.02)
Retreatment for SUI	5/151 (3.3)	1/142 (0.7)	.104*	–2.6 (–0.06 to 0.00)
Pessary	0	0	—	—
Sling	1 (0.7)	0	1.000 [§]	—
Bulking	3 (1.9)	1 (0.7)	.623 [§]	—
Other	1 (0.7)	0	1.000 [§]	—
Postoperative urinary retention [†]	8/156 (5.1) [†]	1/143 (0.7)	.037 [§]	–4.4 (–0.08 to –0.1)
Catheterization at 6 wk	7 (4.5)	1 (0.7)	.077 [§]	—
Catheterization beyond 6 wk	4 (2.6)	0	.123 [§]	—
Surgical sling release	12 (7.7)	0	.000 [§]	—

SUI, stress urinary incontinence; OAB, overactive bladder.

Data are n (%) or n/N (%) unless otherwise specified.

* Pearson Chi-square test.

[†] Owing to the fact that participants contributed to the composite only once, the numbers in the overall composite and thematic component subcategories may have numbers that do not add up to the category above it.

[‡] Sample sizes shown in each cell. These vary owing to missing data as a result of partial follow-up at 12 months for some individuals, and the denominator may differ in individual categories.

[§]Fisher's exact test

are improved by using multiple sites and surgeons.¹⁹ It is possible that the results of this trial may apply unpredictably to surgeons with less training or lower clinical volumes. Additionally, it is possible that the results do not apply to younger patient populations, predominantly non-white groups, or those at the extremes of body habitus (underweight, morbidly obese) because they are underrepresented. Additionally, owing to exclusion criteria, the results cannot be extrapolated to those with more complicated incontinence symptoms, previous surgeries for SUI, and voiding dysfunction.

The differences in the primary composite outcome were a result of lower rates of urinary retention in the Babcock group and a slightly higher proportion of women with a positive cough stress test in the Scissor group. It is difficult to explain how a technique that appeared to be more restrictive and obstructive can also result in more objective failures by Cough Stress Test. It is possible that this finding is a type I statistical error. The final sensitivity analysis removing women who underwent sling lysis or retreatment resulted in the difference in positive cough stress tests no longer being statistically significant. In light of the fact that patient-reported cure of SUI and the proportion of women who demonstrated 1 g or more of urine lost with pad testing did not differ between the

two groups, the authors have interpreted the sensitivity analyses to mean that, clinically, the Scissor and Babcock techniques provide similar rates of SUI cure and that one is not superior to the other in term of cure. The rates of cure described in this trial are also comparable with the findings of prior clinical trials of retropubic midurethral slings,^{10,11} suggesting the results of this trial are reliable and not discrepant from the existing literature.^{10,11}

The MUST trial met its primary endpoint, demonstrating an improved rate of “abnormal bladder function” at 12 months postoperative for the Babcock method. Based on the results, the authors feel comfortable advocating the use of Babcock technique in clinical practice. Surgeons may choose to use the technique as a broad practice pattern for all patients, or the information from this trial can be used to tailor tensioning by certain patient factors. For example, those at a high risk of erosion (eg, smokers, younger patients, concurrent pelvic organ prolapse surgery)^{1,4,5} may have their midurethral slings tensioned by the Scissor technique. Those who are at higher risk of urinary retention or who would be unable to perform catheterization should transient urinary retention occur (eg, those with musculoskeletal issues, obesity, anxiety) could have their midurethral slings tensioned by Babcock technique.

Table 4. Secondary Outcomes at 12-Month Follow-up

Secondary Outcome	Scissor Tensioning	Babcock Tensioning	P	Difference (95% CI)
Questionnaire scores	n=140	n=145		
ISI	2 (0–4)	1 (0–4)	.249*	–1 (–1.59 to 0.41)
UDI-6	8.3 (4.2–25)	8.3 (0–22.9)	.397*	0 (–6.65 to 6.65)
IIQ-7	0 (0–14.3)	0 (0–9.5)	.228*	0 (–1.90 to 1.90)
ICIQ-FLUTS LF	13 (8–20)	11 (7–16)	.076*	–1 (–3.40 to 1.41)
Pad test	0.1 (0–0.4) (n=129)	1.1 (0–0.6) (n=125)	.895*	0 (–0.08 to 0.08)
1 g or more lost	23/129 (17.8%)	20/125 (16.0%)	.698 [†]	1.8% (–0.21 to 0.24)
Mesh exposure	1 (0.7%) (n=134)	7 (5.3%) (n=132)	.030 [‡]	–4.6% (–0.09 to –0.01)
Healed with vaginal estrogen	1 (0.7%)	1 (0.8%)	1.000 [‡]	—
Required surgery	0	5 (3.8%)	.023 [‡]	—
Other	0	1 (0.8%)	1.000 [‡]	—
New treatment for OAB after midurethral sling	n=155	n=151		
New prescription for oral OAB medication	29 (18.7%)	13 (8.6%)	.010 [†]	–10.1% (–0.18 to –0.03)
New treatment with bladder Botox	6 (3.9%)	2 (1.4%)	.283 [‡]	–2.5% (–0.06 to 0.01)
Uroflow parameters	n=115	n=124		
Peak flow rate (mL/sec)	25.4±11.1	28.5±12.9	.045 [†]	3.03 (0.06–6.01)
Flow pattern			.040*	10.76% (0.01–0.21)
Obstructed	30/115 (26.1%)	19/124 (15.3%)		
Postvoid residual (mL)	43.6±87.7	20.8±40.7	.009 [†]	–22.78 (–39.73 to –5.84)

ISI, Incontinence Severity Index; UDI-6, Urinary Distress Index; IIQ-7, Incontinence Impact Questionnaire; ICIQ-FLUTS LF, International Consultation on Incontinence Questionnaire Female Lower Urinary Tract Symptoms Long Form Module; OAB, overactive bladder.

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

Sample sizes shown in each cell. These vary owing to missing data.

* Wilcoxon-Mann-Whitney test.

[†] Pearson χ^2 test.

[‡] Fisher exact test.

Additionally, the Babcock technique may have particular utility for learners and low volume surgeons, because the “perfect” tensioning is generally felt to be an intuitive approach that comes with experience. This is evidenced by the fact that low volume surgeons are associated with higher rates of revision.^{1,20} The use of the Babcock technique may alleviate this increased risk. Anecdotally, the authors involved in this trial continue to use both techniques in their high volume practices, but have found the Babcock technique to be a particularly valuable maneuver when there is suboptimal visualization owing to body habitus, redundant vaginal tissue, and treating those with higher than average blood loss where the ability to truly visualize the tensioning provided by a Scissor spacer would be difficult.

In summary, Scissor and Babcock techniques of retropubic midurethral sling tensioning provide similar and high rates of SUI cure. Surgeons should consider adopting multiple methods of tensioning in their practice and apply techniques thoughtfully for personalized care, because differences in the

postoperative course exist between different techniques.

REFERENCES

- Brennand EA, Quan H. Evaluation of the effect of surgeon's operative volume and specialty on likelihood of revision after mesh midurethral sling placement. *Obstet Gynecol* 2019;133:1099–108.
- GuroI-Urganci I, Geary RS, Mamza JB, Duckett J, El-Hamamsy D, Dolan L, et al. Long-term rate of mesh sling removal following midurethral mesh sling insertion among women with stress urinary incontinence. *JAMA* 2018;320:1659–69.
- Brennand EA, Tang S, Birch C, Murphy M, Ross S, Robert M, et al. Five years after midurethral sling surgery for stress incontinence: obesity continues to have an impact on outcomes. *Int Urogynecol J* 2017;28:621–8.
- Jonsson Funk M, Siddiqui NY, Pate V, Amundsen CL, Wu JM. Sling revision/removal for mesh erosion and urinary retention: Long-term risk and predictors. *Am J Obstet Gynecol* 2013;208:73.e1–7.
- Welk B, Al-Hothi H, Winick-Ng J. Removal or revision of vaginal mesh used for the treatment of stress urinary incontinence. *JAMA Surg* 2015;150:1167–75.
- Sung VW, Rogers ML, Myers DL, Clark MA. Impact of hospital and surgeon volumes on outcomes following pelvic reconstructive surgery in the United States. *Am J Obstet Gynecol* 2006;195:1778–83.

7. Schorge JO, Schaffer JJ, Halvorson LM, Hoffman MD, Bradshaw KD, Cunningham FG. Surgeries for female pelvic reconstruction. In: Williams gynecology. 1st ed. New York: McGraw Hill; 2008.
8. Brennand EA, Kim-Fine S. A randomized clinical trial of how to best position retropubic slings for stress urinary incontinence: development of a study protocol for the Mid-Urethral Sling Tensioning (MUST) trial. *Contemp Clin Trials Commun* 2016;3:60–4.
9. Chang OH, Hacker MR, Rosenblatt PL, Neo D, Von Barga E, Berrahou I, et al. Comparing postoperative voiding dysfunction after mid-urethral sling using either a Babcock or Kelly clamp tensioning technique. *Int Urogynecol J* 2019;30:301–5.
10. Barber MD, Kleeman S, Karram MM, Paraiso MF, Walters MD, Vasavada S, et al. Transobturator tape compared with tension-free vaginal tape for the treatment of stress urinary incontinence: a randomized controlled trial. *Obstet Gynecol* 2008;111:611–21.
11. Ross S, Robert M, Swaby C, Dederer L, Lier D, Tang S, et al. Transobturator tape compared with tension-free vaginal tape for stress incontinence: a randomized controlled trial. *Obstet Gynecol* 2009;114:1287–94.
12. Abrams P, Avery K, Gardener N, Donovan J. The international consultation on incontinence modular questionnaire: www.icq.net. *J Urol* 2006;175:1063–6.
13. Uebersax JS, Wyman JF, Shumaker SA, McClish DK, Andrew Fantl J. Short forms to assess life quality and symptom distress for urinary incontinence in women: the incontinence impact questionnaire and the urogenital distress inventory. *Neurourol Urodyn* 1995;14:131–9.
14. Guralnick ML, Fritel X, Tarcan T, Espuna-Pons M, Rosier PFWM. ICS Educational Module: cough stress test in the evaluation of female urinary incontinence: introducing the ICS-uniform cough stress test. *Neurourol Urodyn* 2018;37:1849–55.
15. Abrams P, Blaivas JG, Stanton SL, Andersen JT. The standardization of terminology of lower urinary tract function recommended by the international continence society. *Int Urogynecol J* 1990;1:45–58.
16. Ward K, Hilton P. Prospective multicenter randomised trial of tension-free vaginal tape and colposuspension as primary treatment for stress incontinence. *Br Med J* 2002;325:67–70.
17. Ward LM, Gaboury I, Ladhani M, Zlotkin S. Vitamin D-deficiency rickets among children in Canada. *CMAJ* 2007;177:161–6.
18. Zwarenstein M, Treweek S, Gagnier JJ, Altman DG, Tunis S, Haynes B, et al. Improving the reporting of pragmatic trials: an extension of the CONSORT statement. *BMJ* 2008;337:1223–6.
19. Rothwell PM. Factors that can affect the external validity of randomised controlled trials. *PLoS Clin Trials* 2006;1:e9.
20. Berger AA, Tan-Kim J, Menefee SA. Surgeon volume and reoperation risk after midurethral sling surgery. *Am J Obstet Gynecol* 2019;221, 523.e1–8.

Authors' Data Sharing Statement

Will individual participant data be available (including data dictionaries)? Yes.

What data in particular will be shared? *Individual participant data that underly the results reported in this article, after deidentification (text, tables, figures).*

What other documents will be available? *Study protocol, statistical analysis plan.*

When will data be available (start and end dates)? *Beginning 12 months and ending 36 months following article publication.*

By what access criteria will data be shared (including with whom, for what types of analyses, and by what mechanism)? *Following approval by a relevant institutional review board of a methodologically sound proposal, data will be available directly from the lead author to investigators at academic institutions.*

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