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## Demographic and Clinical Predictors of Treatment Failure One Year After Midurethral Sling Surgery

Holly E. Richter<sup>1</sup>, Heather J. Litman<sup>2</sup>, Emily S. Lukacz<sup>3</sup>, Larry T. Sirls<sup>4</sup>, Leslie Rickey<sup>5</sup>, Peggy Norton<sup>6</sup>, Gary E. Lemack<sup>7</sup>, Stephen Kraus<sup>8</sup>, Pamela Moalli<sup>9</sup>, Mary Pat Fitzgerald<sup>10</sup>, Kimberly J. Dandreo<sup>2</sup>, Liyuan Huang<sup>2</sup>, and John W. Kusek<sup>11</sup> for the Urinary Incontinence Treatment Network\*

<sup>1</sup> University of Alabama at Birmingham, Birmingham, AL

<sup>2</sup> New England Research Institute, Watertown, MA

<sup>3</sup> University of California San Diego, San Diego, CA

<sup>4</sup> William Beaumont Hospital, Royal Oak, MI

<sup>5</sup> University of Maryland, Baltimore, MD

<sup>6</sup> University of Utah, Salt Lake City, UT

<sup>7</sup> University of Texas Southwestern, Dallas TX

<sup>8</sup> University Texas San Antonio, San Antonio, TX

<sup>9</sup> Magee Women's Hospital, Pittsburgh, PA

<sup>10</sup> Loyola University, Maywood, IL

<sup>11</sup> National Institute of Diabetes, Digestive and Kidney Diseases

### Abstract

**Objective**—To identify clinical and demographic factors predictive of midurethral sling failure.

**Methods**—Overall treatment failure was defined by one or more of the following objective outcomes: a positive stress test, positive 24-hour pad test or re-treatment for stress urinary incontinence (SUI); subjective outcomes: self reported SUI by the Medical, Epidemiologic and Social Aspect of Aging questionnaire (MESA), incontinent episodes by 3-day diary, or retreatment for SUI, or a combination of these. Logistic regression models adjusting for sling type and clinical site were used to predict odds of overall treatment failure after univariable analysis. Models were also fit to compare factors associated with objective failure versus subjective failure only.

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Corresponding Author: Holly E. Richter, PhD, MD, 619 20<sup>th</sup> St. South, 176 F, Suite 10382, Birmingham, AL 35249, Tel: 205-934-1704, Fax: 205-975-8893, hrichter@uab.edu.

\*For a list of other members of the NICHD MFMU, see the Appendix online at <http://links.lww.com/xxx>.

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**Results**—Prior UI surgery (odds ratio [OR] [95% CI], 1.99 [1.14, 3.47]); maximum Q-tip excursion < 30° (OR 1.89 [1.16, 3.05]); MESA urge score per 10 points (OR 1.97 [1.21, 3.21]); and pad weight per 10g (OR 1.06 [1.02, 1.10]) were predictors of overall failure. Having concomitant surgery (OR=0.44 [0.22,0.90]) was predictive of subjective failure only rather than objective failure. Age per 10 years (OR=1.48 [1.14, 1.90]); Urogenital Distress Inventory score per 10 points (OR=1.09[1.02–1.17]); pad weight per 10g (OR=1.05 [1.01, 1.10]) were predictive of objective failure compared to subjective failure only. Associations of risk factors and failure were similar independent of sling type (retropubic or transobturator).

**Conclusion**—Twelve months after surgery, risk factors for overall and objective treatment failure were similar in women undergoing retropubic and transobturator sling procedures. This information may assist in counseling patients regarding efficacy of sling procedures and in setting expectations for women at increased odds for treatment failure.

## Introduction

Midurethral slings are the most frequently performed surgeries in women with stress urinary incontinence (SUI) in the United States. Despite their popularity, information characterizing those women most likely to benefit from these surgeries is meager and conflicting. Possible reasons for this include use of a wide variety of non-comparable outcome measures, non-uniform assessment of subjects and inadequate sample size. Among clinical and demographic factors, increasing age,(1,2) preoperative use of anticholinergic medications for overactive bladder symptoms,(1) mixed incontinence,(3,4) urge incontinence and comorbid disease,(5) concurrent surgery for pelvic organ prolapse,(1,3) bladder neck immobility,(4) obesity, (3) and prior continence surgery (2,6) have all been suggested as predictors of failure with midurethral sling surgery. These associations have not been confirmed or explored by others.(7)

Larger, prospective studies with well-characterized patients are needed to confirm factors that may predict outcomes with mesh slings. One such study, the Trial of Midurethral Slings (TOMUS), compared efficacy between the retropubic and transobturator midurethral slings at 12 months in women with stress predominant urinary incontinence (UI). The rates of objectively assessed success (outcomes included a 24 hour pad test, bladder fill stress test and retreatment) were considered equivalent between the two approaches at 12 months. Although the rates of subjectively assessed success (outcomes included bladder diary, SUI symptoms and retreatment) were similar, they did not meet the predetermined criteria for equivalence.(8) This analysis examines baseline demographic and clinical factors as possible predictors of “overall” surgical failure (objective and/or subjective failure) versus treatment success. We also wished to explore those factors associated with objective versus subjective failure, where objective failure may define a higher threshold for failure, potentially reflecting failure more directly aligned with successful placement of the sling and the mechanism of action of the procedure itself.

## Materials & Methods

The design and primary results of this two-arm randomized equivalence trial comparing retropubic (RMUS) to transobturator (TMUS) midurethral slings have been described previously.(8,9) Women aged 21 years or older planning stress incontinence surgery were invited to participate. Eligibility requirements included pure or predominant stress incontinence symptoms for at least three months and a positive urinary stress test at a bladder volume of 300 mL or less. Women were randomized to a RMUS or TMUS midurethral sling. Randomization was performed after anesthesia was administered with the use of a permuted-block randomization schedule stratified according to clinical site.

Institutional Review Board approval was obtained at nine clinical sites and the coordinating center. Written informed consent was obtained. An independent data and safety monitoring board reviewed the progress, interim results and safety of the study.

Definitions of clinical terms, methods of evaluation, and key surgical elements, including cystoscopic evaluation, were standardized across 9 participating sites.(10,11) The Tension-Free Vaginal Tape (TVT) (Gynecare™) was used as the retropubic sling, and the Tension-Free Vaginal Tape Obturator (TOT) (Gynecare™) (in-to-out) or the Monarc (American Medical System™) (out-to-in) was used as the transobturator midurethral sling. Surgeons declared which transobturator approach they would utilize prior to trial initiation should the subject be randomized to the TMUS arm. Concomitant vaginal surgery was permitted.

Surgical success was determined at 12 months post randomization by the following outcome measures of objective failure: a positive provocative stress test at 300 mL *or* a positive 24-hour pad test ( $\geq 15$  mL leakage over 24 hours) *or* retreatment for stress incontinence and subjective measures including a self-reported stress-type UI symptoms on the Medical Epidemiological and Social Aspects of Aging (MESA) (12) questionnaire *or* leakage on a 3-day voiding diary *or* retreatment (behavioral, pharmacologic or surgical) for stress incontinence. Women were considered overall failures if they experienced either objective or subjective failure or both. Data were collected pre-operatively, 2 and 6 weeks, and 6 and 12 months post operatively by interview and clinical examination. For this analysis, potential variables thought to be associated with treatment failure were sociodemographic characteristics (age, race/ethnicity, education, marital status); medical/surgical history (body mass index, smoking status, menopausal status/hormone therapy(HT), previous prolapse surgery, estimated blood loss during sling surgery, prior UI surgery, fecal incontinence symptoms, number of vaginal deliveries); characteristics of UI (self-reported frequency of stress and urge incontinence symptoms from the MESA questionnaire (12); symptom bother and incontinence-related quality of life as measured by the Urogenital Distress Inventory (UDI) and Incontinence Impact Questionnaire (IIQ) (13); number of incontinence episodes/day by 3-day voiding diary; quantity of urine leakage from 24-hour pad test (14); physical examination findings (urethral hypermobility measured by the Q-tip test (15) with Q-tip delta and maximum straining considered; pelvic floor muscle strength (16); pelvic organ prolapse (17); post void residual at discharge ( $\leq 100$  mL,  $>100$  mL) and outcome of baseline empty bladder stress test (positive/negative)). Performance of concomitant surgery (yes/no) and number of co-morbid illnesses reported (0, 1, 2 or more) was included. (18,19)

To identify predictors of treatment failure, univariable logistic regression models were fit modeling the probability of overall failure and objective failure as a function of each covariate separately, adjusting for treatment group (RMUS and TMUS approaches) and site. The models predicting overall failure compare the women with overall failure to those with overall success. A sub-analysis of the women with objective failure was performed where models were fit to compare women with objective failure to those with subjective failure but objective success. Both continuous and categorical predictors were considered. Odds ratios (ORs) and 95% confidence intervals (CIs) described the associations between clinical parameters and the outcomes. Based on significance at the 0.05 level from the univariable logistic regression models and clinical relevance, multivariable logistic regression models were fit for each defined outcome. To assess whether the relationships between the predictors and failure were similar for each of the treatment groups, interaction terms between each predictor and treatment were considered. Interaction terms between significant main effects were also tested for inclusion in the multivariable models. Hosmer-Lemeshow goodness of fit tests were calculated to assess the fit of the models. A 5% two-sided significance level was used for all statistical testing. Data from women with missing

covariate values were included when possible (e.g. available case analysis was used). Analyses were performed using SAS Version 9.2 (SAS Institute, Inc. Cary, NC).

## Results

Baseline data were obtained from 597 women. Of those, 565 (95%) were assessed for surgical success at 12 months post-surgery, 280 (94%) of subjects in the RMUS arm and 285 (95%) of subjects in the TMUS arm. Overall treatment failure was seen in 260 (46.0%) subjects as compared to treatment success in 305 (54.0%) subjects (Figure 1). Of the overall failures, 130 failed by subjective measures only; 109 failed by both objective and subjective measures and 15 by objective measures only.

Baseline characteristics of women with overall failure compared to those with overall success are noted in Table 1. Univariable and multivariable analyses controlling for treatment group and clinical site for each of these baseline characteristics are reported in Table 2. Increasing age and body mass index, prior incontinence surgery, q-tip excursion and maximum straining angle of  $< 30^\circ$ ; as well as higher baseline leakage, Brink score, pad weight and symptom scores (UDI, IIQ, and MESA questionnaires) were each associated with increased odds of overall failure on initial bivariate analysis. Multivariable logistic regression analysis showed that women who had prior UI surgery had an increased odds of overall failure of approximately two times that of women who had no prior UI surgery controlling for other factors. Women with a maximum Q-tip excursion  $< 30^\circ$  (less bladder neck mobility), had a nearly two-fold increased odds of failure compared to those with hypermobility. Baseline severity measures including increasing MESA urge scores and increasing pad weights were also associated with overall failure. For each 10 point increase in urge score the odds of overall failure nearly doubled and for each 10 gram increase in pad weight the odds of overall failure increased by approximately 6%.

We also explored differences in baseline characteristics of those women with objective failure consisting of a positive stress test, pad test and retreatment (regardless of subjective report) compared to those with subjective failure only (negative stress and pad tests) (Table 3). In univariable analysis subjects with prior incontinence surgery, concomitant surgery, presence of comorbid conditions, age, and baseline UDI, IIQ, MESA urge and stress, and increasing pad weight were significantly associated with objective failure compared to subjects with only subjective failure. Multivariable analyses revealed that for each 10 year increase in age there was a nearly 50% increase in the odds of objective failure compared to subjective only failure controlling for other factors. Increased baseline UDI score and pad weight also predicted nearly a 5–10% increase in the odds of objective failure for each 10 unit increase in value. Further, women who had concomitant surgery were half as likely to fail objectively compared to women who failed subjectively (Table 4). Associations of risk factors with overall and objective/subjective failure were similar for both sling types.

## Discussion

The clinical evaluation of women with UI includes patient history, physical examination and measures of incontinence severity. An understanding of those patient factors associated with treatment failure and success can help us more robustly counsel patients regarding realistic expectations from midurethral sling surgery for stress incontinence. In this analysis we hypothesized that objective and subjective outcome measures capture different post-operative processes and those that failed objectively may be a more “severe” failure or have a greater degree of failure. Objective measures may be a more sensitive reflection of the sling procedures mechanism of action, with the dynamic urethral kinking that occurs with the TVT serving as a fulcrum reflecting surgical technique and quality of host tissue in-

growth. (20) An understanding of the types of patients at risk for these types of failures may help us more effectively target patients for these or other treatment options. Subjective failures may capture urge symptoms, less severe leakage or other perceived leakage that may or may not be related to sling function in preventing SUI.

In our study, women who had prior UI surgery had nearly twice the odds of overall failure compared to women having their first surgery for SUI. Previous incontinence surgery as a risk factor for failure after MUS has been described by several authors (2,3,6) and may be due to scarring, nerve damage during periurethral dissection, or more severe neuromuscular compromise. We observed that women with less urethral mobility (Q-tip max straining angle  $<30^\circ$  had about twice the odds of overall failure than patients with more urethral mobility (Q tip angle  $\geq 30$  degrees) despite the fact that pre-operative urethral hypermobility was not associated with objective failure. Others have reported similar findings. (21,22) For example, Liapis et al (21) observed that women with a less mobile urethra (maximum Q-tip straining angle  $< 30^\circ$ ) undergoing TVT for recurrent SUI had a 50% failure rate compared to 10% failure rate in patients with greater mobility (Q-tip excursion  $\geq 30^\circ$ ). Therefore, patients with less mobility may have a more neurologically impaired baseline urethral function and and other treatments such as bulking agents may be a more appropriate consideration.

For every 10 point increase in the baseline MESA urge incontinence score the odds of overall failure nearly doubled. In addition, for every 10 point increase in urge incontinence both as measured by the UDI, the odds of objective failure increased by nearly 10%. We and others have also previously described this association. (23,5,24) To this point, Holmgren reported the long-term cure rate after TVT in women with mixed urinary incontinence (MUI) was 30% at 8 years compared to an 85% cure rate in women with pure SUI.(24) However, others have found the presence of urge symptoms in stress-predominant MUI does not negatively impact success. (25,26) Whether patients with more urgency incontinence symptoms reflects a more complex neuromuscular dysfunction is not clear. Nonetheless, patients with MUI should be strongly counseled about the possibility of lower cure rates and perhaps more robust perioperative treatment with behavioral and/or medical therapy should be considered.

We found that greater pad weight at baseline increased the odds of both overall failure and objective failure after MUS and this has been corroborated by others.(2) In the current study pad weight was the only clinical measure associated with both overall and objective surgical failure. Perhaps the use of pad testing should be used more frequently in the evaluation of our patients considering midurethral sling surgery for stress incontinence.

Concomitant prolapse surgery was not associated with overall failure, but did decrease the odds of objective as compared to subjective failure by nearly 50%. Similarly, a large retrospective study showed that concomitant pelvic organ prolapse (POP) surgery decreased the likelihood of failure of retropubic or transobturator MUS (3). These data conflict with another study that reported concurrent POP surgery increased the odds of developing any recurrent incontinence.(1)

Strengths of the study included its multicenter design including sites throughout the United States, with a variety of urology and urogynecology surgeons making our study more generalizable. We included extensive preoperative clinical and demographic variables, used clearly defined validated outcome measures and had a high rate of ascertainment at 12 month post-surgery. In the patient evaluation process for urinary incontinence, after obtaining the baseline clinical evaluation and examination, urodynamic testing is often used to confirm the diagnosis or provide additional functional and/or severity information. This



current report only focuses on those demographic and clinical factors that may predict failure.

In conclusion, women with prior incontinence surgery, urethral hypomobility, and more severe urge urinary incontinence symptoms demonstrated greater overall odds of failure 12 months after undergoing RMUS or TMUS surgery. Pad weight testing seems to be a powerful predictor of failure. Although surgical history and urethral mobility are not modifiable risk factors, this information will assist in counseling patients regarding the efficacy of these procedures, help identify patients who may benefit from additional or alternate therapies and assist in setting appropriate expectations for women with increased odds for treatment failure.

## Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

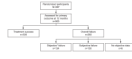
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**Figure 1.** Trial of Midurethral Slings (TOMUS) patient population with treatment failure information. Comparisons focus on 1) treatment success and overall failure; 2) objective and subjective failures. \*109 were objective and subjective failures; 15 were objective failures only.



**Table 1**

Characteristics of Women with Overall Failure versus Overall Success

Predictor	Overall Failure (n=260)	Overall Success No (n=305)
<b>Treatment Group</b>		
RMUS	122(47%)	158(52%)
TMUS	138(53%)	147(48%)
<b>Race</b>		
Hispanic	28(11%)	38(12%)
Non-hispanic White	210(81%)	239(78%)
Non-hispanic Black	8(3%)	9(3%)
Non-hispanic Other	14(5%)	19(6%)
<b>Marital Status</b>		
Not married	87(33%)	85(28%)
Married/Living as married	173(67%)	220(72%)
<b>Education</b>		
<HS	10(4%)	19(6%)
HS/GED	64(25%)	78(26%)
>HS	99(38%)	108(35%)
BA/BS/Grad/Prof	87(33%)	100(33%)
<b>Smoking</b>		
Never smoked	143(55%)	163(53%)
Former smoker	80(31%)	103(34%)
Current smoker	37(14%)	39(13%)
<b>HRT Use</b>		
No	118(45%)	115(38%)
Yes	77(30%)	88(29%)
Pre-Menopausal	64(25%)	101(33%)
<b>Previous Prolapse Surgery</b>		
No	245(95%)	295(97%)
Yes	14(5%)	9(3%)
<b>Prolapse Stage</b>		
Stage 0-1	110(42%)	140(46%)
Stage 2	129(50%)	140(46%)
Stage 3+	21(8%)	25(8%)
<b>Prior UI Surgery</b>		
No	210(81%)	278(91%)
Yes	49(19%)	26(9%)
<b>Fecal Incontinence Symptoms</b>		
No	195(75%)	234(77%)
Yes	65(25%)	71(23%)
<b>Concomitant Surgery</b>		
No	200(75%)	225(74%)

Predictor	Overall Failure (n=260)	Overall Success No (n=305)
Yes	60(25%)	80(26%)
<b>Vaginal Deliveries</b>		
Never delivered	31(12%)	36(12%)
One delivery	50(19%)	47(15%)
Two deliveries	66(25%)	110(36%)
Three deliveries	69(27%)	68(22%)
Four or more deliveries	44(17%)	44(14%)
<b>PVR at Discharge &gt;100</b>		
No	196(79%)	221(75%)
Yes	51(21%)	75(25%)
<b>Number of Comorbidities</b>		
0	184(71%)	234(77%)
1	48(18%)	42(14%)
2+	28(11%)	29(10%)
<b>Qtip Delta&lt;30</b>		
No	157(60%)	225(74%)
Yes	103(40%)	80(26%)
<b>Qtip Max Straining&lt;30</b>		
No	201(77%)	263(86%)
Yes	59(23%)	42(14%)
<b>Empty bladder stress test</b>		
Positive	131(51%)	141(47%)
Negative	128(49%)	162(63%)
<b>Age, years</b>	54.4(11.4)	52.2(10.2)
<b>BMI</b>	31.1(6.9)	29.6(6.3)
<b>EBL During Sling, ml</b>	42.9(50.4)	43.6(40.4)
<b>POPQ Ba</b>	-1.2(1.4)	-1.3(1.6)
<b>POPQ Bp</b>	-1.9(1.3)	-2.0(1.5)
<b>POPQ Gh</b>	3.5(1.0)	3.4(1.1)
<b>Brink score</b>	8.6(2.0)	8.9(2.0)
<b>UDI Total</b>	139.9(43.3)	129.3(44.6)
<b>IIQ Total</b>	163.0(98.8)	139.4(92.5)
<b>Stress Score</b>	20.1(4.5)	18.8(4.7)
<b>Urge Score</b>	7.2(4.0)	5.6(3.7)
<b>Leaks/day</b>	3.9(3.2)	2.9(2.7)
<b>Pad Weight, g</b>	50.2(88.9)	24.7(39.7)

RMUS-retropubic midurethral sling; TMUS-transobturator midurethral sling; HS-high school; GED-graduate equivalency degree; BA/BS-bachelors degree; Grad-post-graduate degree; Prof-professional degree; HRT-hormone replacement therapy; UI-urinary incontinence; PVR-postvoid residual; BMI-body mass index; EBL-estimated blood loss; ml-milliliter; g-grams.

**Table 2**

Bivariate and Multivariable Associations of Potential Predictors of Overall Failure versus Overall Success, Controlling Treatment Group and Site

Predictor	Univariable Analyses		Final Multivariable Analysis*	
	p-value	Adjusted Odds Ratio (95%CI)	p-value	Adjusted Odds Ratio (95%CI)
<b>Treatment Group</b>	0.25		0.44	
RMUS		Reference		Reference
TMUS		1.22(0.87–1.70)		1.15(0.81–1.63)
<b>Race</b>	0.53			
Hispanic		Reference		
Non-hispanic White		1.56 ( 0.85–2.85)		
Non-hispanic Black		1.54 ( 0.50–4.70)		
Non-hispanic Other		1.27 ( 0.52–3.12)		
<b>Marital Status</b>	0.15			
Not married		Reference		
Married/Living as married		0.76 ( 0.53–1.10)		
<b>Education</b>	0.44			
<HS		Reference		
HS/GED		1.56 ( 0.67–3.64)		
>HS		1.78 ( 0.78–4.05)		
BA/BS/Grad/Prof		1.75 ( 0.76–4.03)		
<b>Smoking</b>	0.79			
Never smoked		Reference		
Former smoker		0.93 ( 0.64–1.35)		
Current smoker		1.12 ( 0.67–1.87)		
<b>HRT Use</b>	0.11			
No		Reference		
Yes		0.87 ( 0.57–1.34)		
Pre-Menopausal		0.64 ( 0.42–0.98)		
<b>Previous Prolapse Surgery, yes</b>	0.12	1.99 ( 0.83–4.75)		
<b>Prolapse Stage</b>	0.60			
Stage 0–1		Reference		
Stage 2		1.18 ( 0.83–1.70)		
Stage 3+		0.96 ( 0.50–1.87)		
<b>Prior UI Surgery, yes</b>	0.0002	2.69 ( 1.59–4.55)	0.01	1.99(1.14–3.47)
<b>Fecal Incontinence Symptoms, yes</b>	0.61	1.11 ( 0.75–1.64)		
<b>Concomitant Surgery, yes</b>	0.32	0.81 (0.54–1.22)		
<b>Vaginal Deliveries</b>	0.19			
Never delivered		Reference		
One delivery		1.11 ( 0.59–2.11)		
Two deliveries		0.68 ( 0.38–1.22)		
Three deliveries		1.13 ( 0.62–2.06)		

Predictor	Univariable Analyses		Final Multivariable Analysis*	
	p-value	Adjusted Odds Ratio (95%CI)	p-value	Adjusted Odds Ratio (95%CI)
Four or more deliveries		1.00 ( 0.51–1.94)		
<b>PVR at Discharge, yes &gt;100</b>	0.21	0.77 ( 0.51–1.16)		
<b>Number of Comorbidities</b>	0.20			
0		Reference		
1		1.52 ( 0.95–2.42)		
2+		1.22 ( 0.69–2.15)		
<b>Qtip Delta&lt;30, yes</b>	0.001	1.95 (1.32–2.89)		
<b>Qtip Max Straining&lt;30, yes</b>	0.005	1.97 (1.23–3.14)	0.01	1.89(1.16–3.05)
<b>Empty Bladder Stress Test</b>	0.22			
Positive		1.24 (0.88–1.74)		
Negative		Reference		
<b>Age (10 per unit), years</b>	0.02	1.21 ( 1.03–1.42)		
<b>BMI</b>	0.005	1.04 ( 1.01–1.07)		
<b>EBL During Sling (10 per unit), ml</b>	0.84	1.00 ( 0.96–1.04)		
<b>Brink Score</b>	0.045	0.91 ( 0.84–1.00)		
<b>UDI Total (10 per unit)</b>	0.004	1.06 ( 1.02–1.10)		
<b>IIQ Total (10 per unit)</b>	0.006	1.03 ( 1.01–1.04)		
<b>Stress Score(10 per unit)</b>	0.002	1.85 ( 1.26–2.70)		
<b>Urge Score(10 per unit)</b>	<.0001	2.88 ( 1.83–4.55)	0.007	1.97(1.21–3.21)
<b>Leaks/day</b>	0.0005	1.12 ( 1.05–1.19)		
<b>Pad Weight (10 per grams)</b>	<.0001	1.07 ( 1.04–1.11)	0.003	1.06(1.02–1.10)

\* Hosmer and Lemeshow Goodness-of-Fit Test p-value=0.70

RMUS-retropubic midurethral sling; TMUS-transobturator midurethral sling; HS-high school; GED-graduate equivalency degree; BA/BS-bachelors degree; Grad-post-graduate degree; Prof-professional degree; HRT-hormone replacement therapy; UI-urinary incontinence; PVR-postvoid residual; BMI-body mass index; EBL-estimated blood loss; ml-milliliter; UDI-Urogenital Distress Inventory; IIQ-Incontinence Impact Questionnaire.

**Table 3**

Characteristics of Women with Objective Failure versus Subjective Failure &amp; Objective Success

Predictor	Objective Failure (n=124)	Subjective Failure & Objective Success (n=130)
<b>Treatment Group</b>		
RMUS	57(46%)	64(49%)
TMUS	67(54%)	66(51%)
<b>Race/ethnicity</b>		
Hispanic	16(13%)	12(9%)
Non-hispanic White	99(80%)	107(82%)
Non-hispanic Black	4(3%)	3(2%)
Non-hispanic Other	5(4%)	8(6%)
<b>Marital Status</b>		
Not married	46(37%)	38(29%)
Married/Living as married	78(63%)	92(71%)
<b>Education</b>		
<HS	2(2%)	7(5%)
HS/GED	37(30%)	26(20%)
>HS	44(35%)	52(40%)
BA/BS/Grad/Prof	41(33%)	45(35%)
<b>Smoking</b>		
Never smoked	71(57%)	68(52%)
Former smoker	33(27%)	47(36%)
Current smoker	20(16%)	15(12%)
<b>HRT Use</b>		
No	53(43%)	61(47%)
Yes	42(34%)	35(27%)
Pre-Menopausal	28(23%)	34(26%)
<b>Previous Prolapse Surgery</b>		
No	116(94%)	123(95%)
Yes	7(6%)	7(5%)
<b>Prolapse Stage</b>		
Stage 0-1	55(44%)	50(38%)
Stage 2	60(48%)	68(52%)
Stage 3+	9(7%)	12(9%)
<b>Prior UI Surgery</b>		
No	92(75%)	113(87%)
Yes	31(25%)	17(13%)
<b>Fecal Incontinence Symptoms</b>		
No	93(75%)	96(74%)
Yes	31(25%)	34(26%)
<b>Concomitant Surgery</b>		
No	102(82%)	92(71%)

Predictor	Objective Failure (n=124)	Subjective Failure & Objective Success (n=130)
Yes	22(18%)	38(29%)
<b>Vaginal Deliveries</b>		
Never delivered	17(14%)	14(11%)
One delivery	21(17%)	27(21%)
Two deliveries	32(26%)	32(25%)
Three deliveries	34(27%)	33(25%)
Four or more deliveries	20(16%)	24(18%)
<b>PVR at Discharge &gt;100</b>		
No	101(85%)	91(75%)
Yes	18(15%)	31(25%)
<b>Number of Comorbidities</b>		
0	83(67%)	96(74%)
1	22(18%)	25(19%)
2+	19(15%)	9(7%)
<b>Qtip Delta&lt;30</b>		
No	75(60%)	78(60%)
Yes	49(40%)	52(40%)
<b>Qtip Max Straining&lt;30</b>		
No	92(74%)	105(81%)
Yes	32(26%)	25(19%)
<b>Empty bladder stress test</b>		
Positive	66(53%)	62(48%)
Negative	58(47%)	67(52%)
<b>Age, years</b>	57.0(11.7)	52.2(10.5)
<b>BMI</b>	30.9(6.6)	31.3(7.1)
<b>EBL During Sling, ml</b>	45.5(62.1)	41.0(37.3)
<b>POPQ Ba</b>	-1.4(1.3)	-1.1(1.5)
<b>POPQ Bp</b>	-2.0(1.2)	-1.8(1.4)
<b>POPQ Gh</b>	3.4(0.9)	3.5(1.0)
<b>Brink Score</b>	8.6(1.9)	8.5(2.1)
<b>UDI Total</b>	149.3(45.7)	130.4(39.3)
<b>IIQ Total</b>	180.4(99.5)	147.7(95.9)
<b>Stress Score</b>	20.6(4.6)	19.6(4.4)
<b>Urge Score</b>	7.7(4.1)	6.7(3.8)
<b>Leaks/day</b>	4.3(3.4)	3.6(3.1)
<b>Pad Weight, grams</b>	72.7(107.2)	30.2(62.8)

RMUS-retropubic midurethral sling; TMUS-transobturator midurethral sling; HS-high school; GED-graduate equivalency degree; BA/BS-bachelors degree; Grad-post-graduate degree; Prof-professional degree; HRT-hormone replacement therapy; UI-urinary incontinence; PVR-postvoid residual; BMI-body mass index; EBL-estimated blood loss; ml-milliliter; POPQ-pelvic organ prolapse quantification; UDI-Urogenital Distress Inventory; IIQ-Incontinence Impact Questionnaire.



**Table 4**

Bivariate and Multivariable Associations of Potential Predictors of Objective Failure versus Subjective Failure & Objective Success Controlling Treatment Group and Site

Covariable	Univariable Analyses		Final Multivariable Analysis*	
	p-value	Adjusted Odds Ratio (95%CI)	p-value	Adjusted Odds Ratio (95%CI)
<b>Treatment Group</b>	0.43		0.45	
RMUS		Reference		Reference
TMUS		1.23(0.74–2.06)		1.24(0.71–2.17)
<b>Race</b>	0.77			
Hispanic		Reference		
Non-hispanic White		0.94 (0.38–2.30)		
Non-hispanic Black		1.63 ( 0.28–9.56)		
Non-hispanic Other		0.58 ( 0.14–2.41)		
<b>Marital Status</b>	0.20			
Not married		Reference		
Married/Living as married		0.69 ( 0.40–1.21)		
<b>Education</b>	0.14			
<HS		Reference		
HS/GED		5.60 (1.01–31.0)		
>HS		3.12 ( 0.58–16.6)		
BA/BS/Grad/Prof		3.48 ( 0.64–18.8)		
<b>Smoking</b>	0.36			
Never smoking		Reference		
Former smoking		0.71 ( 0.39–1.27)		
Current smoking		1.21 ( 0.55–2.68)		
<b>HRT Use</b>	0.30			
No		Reference		
Yes		1.51 ( 0.80–2.86)		
Pre-Menopausal		0.90 ( 0.47–1.72)		
<b>Previous Prolapse Surgery, yes</b>	0.81	1.16 ( 0.37–3.65)		
<b>Prolapse Stage</b>	0.41			
Stage 0–1		Reference		
Stage 2		0.75 ( 0.43–1.30)		
Stage 3+		0.56 ( 0.20–1.53)		
<b>Prior UI Surgery, yes</b>	0.005	2.74 ( 1.36–5.56)		
<b>Fecal Incontinence Symptoms, yes</b>	0.91	0.97 ( 0.54–1.74)		
<b>Concomitant Surgery, yes</b>	0.03	0.50 ( 0.26–0.95)	0.02	0.44(0.22–0.90)
<b>Vaginal Deliveries</b>	0.48			
Never delivered		Reference		
One delivery		0.47 ( 0.18–1.26)		
Two deliveries		0.68 ( 0.26–1.73)		
Three deliveries		0.73 ( 0.30–1.82)		

Covariable	Univariable Analyses		Final Multivariable Analysis*	
	p-value	Adjusted Odds Ratio (95%CI)	p-value	Adjusted Odds Ratio (95%CI)
Four or more deliveries		0.46 ( 0.17–1.27)		
<b>PVR at Discharge &gt;100, yes</b>	0.12	0.58 ( 0.29–1.15)		
<b>Number of Comorbidities</b>	0.04			
0		Reference		
1		1.21 ( 0.61–2.39)		
2+		3.15 ( 1.29–7.71)		
<b>Qtip Delta&lt;30, yes</b>	0.86	1.05 ( 0.59–1.89)		
<b>Qtip Max Straining&lt;30, yes</b>	0.06	1.90 (0.96–3.74)		
<b>Empty bladder stress test</b>	0.31			
Positive		1.31 (0.78, 2.21)		
Negative		Reference		
<b>Age (10 per unit)</b>	0.0004	1.56 ( 1.22–1.99)	0.003	1.48(1.14–1.90)
<b>BMI</b>	0.86	1.00 ( 0.97–1.04)		
<b>EBL During Sling (10 per unit), ml</b>	0.33	1.03 ( 0.97–1.09)		
<b>Brink Score</b>	0.36	1.06 ( 0.93–1.21)		
<b>UDI Total (10 per unit)</b>	0.001	1.11 ( 1.04–1.18)	0.01	1.09(1.02–1.17)
<b>IIQ Total (10 per unit)</b>	0.008	1.04 ( 1.01–1.07)		
<b>Stress Score(10 per unit)</b>	0.047	1.81 ( 1.01–3.25)		
<b>Urge Score(10 per unit)</b>	0.01	2.35 ( 1.19–4.63)		
<b>Leaks/day</b>	0.12	1.07 ( 0.98–1.16)		
<b>Pad Weight (10 per gram)</b>	0.0007	1.08 ( 1.03–1.12)	0.02	1.05(1.01–1.10)

\* Hosmer and Lemeshow Goodness-of-Fit Test p-value=0.99

RMUS-retropubic midurethral sling; TMUS-transobturator midurethral sling; HS-high school; GED-graduate equivalency degree; BA/BS-bachelors degree; Grad-post-graduate degree; Prof-professional degree; HRT-hormone replacement therapy; UI-urinary incontinence; PVR-postvoid residual; BMI-body mass index; EBL-estimated blood loss; ml-milliliter; POPQ-pelvic organ prolapse quantification; UDI-Urogenital Distress Inventory; IIQ-Incontinence Impact Questionnaire.