

# Female Urology, Urodynamics, Incontinence, and Pelvic Floor Reconstructive Surgery

## Analysis of the Completely Dry Rate Over Time After Mid-urethral Sling in a Real-world Clinical Setting



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<b>OBJECTIVE</b>	To improve patient counseling regarding mid-urethral slings (MUS), we performed an analysis of MUS patients dry at initial follow-up to evaluate probability of remaining dry over time, and analyzed clinical factors potentially influencing the probability of remaining dry.
<b>METHODS</b>	A retrospective review of our prospectively-collected institutional database identified patients who underwent retropubic MUS (RMUS) or transobturator MUS (TMUS) between January 2001 and March 2016 and were completely dry, defined as an answer of “not at all” to UDI-6 question 3, at first follow-up within 1.5 years of surgery. Proportion remaining dry over time was estimated by Kaplan-Meier. Associated factors were evaluated using Cox proportional hazards modeling. Proportion with urge urinary incontinence at time of sling failure was assessed.
<b>RESULTS</b>	Of 1102 patients undergoing MUS, 38.4% returned questionnaires and 47.5% of these were completely dry at initial follow-up (139 RMUS, 62 TMUS). Probability (95% CI, $n$ = total patients) of remaining dry after RMUS at 3, 5, and 10 years was 72% (64%-81%, $n$ = 70), 60% (51%-70%, $n$ = 51), and 26% (18%-43%, $n$ = 17). Probability estimates for TMUS at 3 and 5 years were 74% (62%-88%, $n$ = 27) and 50% (35%-70%, $n$ = 14). Obesity (Hazard ratio 2.22, $P$ = .003) and age (Hazard ratio 1.043, $P$ < .001) were associated with lower probability of remaining dry after RMUS. Of patients no longer completely dry at last follow-up, 72% RMUS and 75% TMUS had urge urinary incontinence.
<b>CONCLUSION</b>	In our real-world cohort, patients who are dry within the first 1.5 years following MUS have $\geq 50\%$ chance of remaining dry for 4 more years. UROLOGY 126: 65–69, 2019. © 2019 Elsevier Inc.

Urinary incontinence is a widespread burden to women, with an estimated prevalence of roughly 28% worldwide.<sup>1</sup> In the United States, stress urinary incontinence (SUI) imparts a significant financial burden and is estimated to cost the healthcare system roughly \$12 billion per year.<sup>2,3</sup> The mid-urethral sling (MUS) is a minimally-invasive treatment option that has shown high satisfaction rates and improvements in quality of life scores in patients with SUI.<sup>4</sup>

Outcomes reported for MUS in the clinical setting may differ from the carefully selected populations studied in randomized controlled trials, limiting the applicability of this data to patient counseling in a real-world clinical setting.

Administrative claims databases can be used to assess outcomes in a large population of women over time, however the outcome measures are limited to reoperation rates, which are not necessarily an accurate measure of success.<sup>5,6</sup> In addition, variable definitions of success after MUS surgery complicate comparisons to real-world clinical populations. Long-term success rates vary from 43% to 92%, depending on the definition of success, characteristics of the patient population, study design, and time frame over which results were determined.<sup>7</sup> Also, patient population can vary by specialty, as recently reported by James et al, who showed that urologists tend to treat more complex patients as compared to gynecologists.<sup>8</sup> For these reasons, preoperative patient counseling regarding the success and durability of MUS surgery can be challenging. In clinical practice, long-term success rates after MUS may be unknown due to loss to follow-up or lack of validated questionnaire use.

In clinical practice, a primary concern for patients is how effective MUS will be for their incontinence and how long they can expect this treatment to remain

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effective. The purpose of this study was to generate information we could use to counsel patients regarding these questions. A clinically-meaningful, yet succinct, measure of success to quantify after MUS surgery is the patient report of being completely dry. To this end, the primary objective of this study was to examine patient-reported dry rates for retropubic MUS (RMUS) and transobturator MUS (TMUS) at our institution over time, using our prospectively-maintained surgical database. The secondary objective was to evaluate the association between selected clinical and demographic factors and the probability of remaining completely dry over time.

## MATERIALS AND METHODS

### Study Design and Patient Selection

This study was approved by our Institutional Review Board (IRB #3011200). To select subjects for inclusion in the study, we conducted a retrospective review of our prospectively-collected institutional database to identify patients who had either a RMUS or TMUS performed by 1 of 4 urologic surgeons between January 1, 2001 and March 30, 2016 for treatment of SUI. The choice of MUS (RMUS or TMUS) was determined by surgeon preference. Demographic and clinical characteristics, such as age, BMI, gravidity, parity, race, and smoking history were recorded for each patient. Preoperative urodynamic evaluation (UDS) was performed according to International Continence Society guidelines, and parameters were recorded as available. The decision to perform UDS was determined by surgeon preference. Valsalva Leak Point Pressure (VLPP) was determined by the vesical pressure at which leakage occurred during a Valsalva maneuver. Detrusor overactivity (DO) was defined as a rise in detrusor pressure that was observed during the filling phase in the absence of change in abdominal pressure.

Patients in our database are routinely mailed questionnaires beginning at 6 months after surgery, and annually thereafter. Questionnaires include the Urogenital Distress Inventory short form (UDI-6), as well as assessments including patient global impression of improvement, patient-reported satisfaction, and an incontinence questionnaire specific to our institution. This institutionally-based questionnaire characterizes the type of incontinence as well as the frequency of incontinence episodes.

Patients were included if they completed at least 1 questionnaire within 1.5 years of surgery as well as 1 additional questionnaire at 2 or more years postsurgery. The 1.5 year period was chosen to allow for some lag time between when patients received their 1 year questionnaire and the time it was returned. When multiple questionnaires were returned, the last one returned was included in the analyses. To do this required the assumption that patients who were not completely dry as related to SUI at one point in time would not become dry at the most recent survey. We defined being completely dry as an answer of “not at all” to the UDI-6 question 3, “Do you experience, and if so, how much are you bothered by leakage related to physical activity, coughing, or sneezing?” This question assesses symptom severity and bother from SUI.<sup>9</sup> Patients who were not dry at initial follow-up were excluded. Patients were deemed to be no longer completely dry at the time of a subsequent SUI surgical procedure or answering at least “slightly” bothered by UDI-6 question 3.

By using only UDI-6 question 3 in our analysis of a patient being completely dry we have limited the possibility that patients

who develop subsequent UUI after MUS would no longer be considered dry despite the absence of SUI. In addition, we then performed an analysis to examine if UUI was present at the time point at which patients were no longer completely dry, as a possible confounding factor. Patients were considered to have urgency at follow-up if they answered anything other than “not at all” on UDI-6 question 2, which pertains to urgency incontinence.

### Statistical Analysis

Age, race, ethnicity, smoking history, obesity (BMI > 30 prior to surgery), gravidity, parity, urodynamic SUI, VLPP (both VLPP < 30 and VLPP < 70), and urodynamic DO were analyzed using time-to-event analysis. Kaplan-Meier analysis was used to estimate overall durability and Cox proportional hazards modeling was used to estimate factor-specific risk. All analyses were performed using R version 3.3.1.<sup>10</sup>

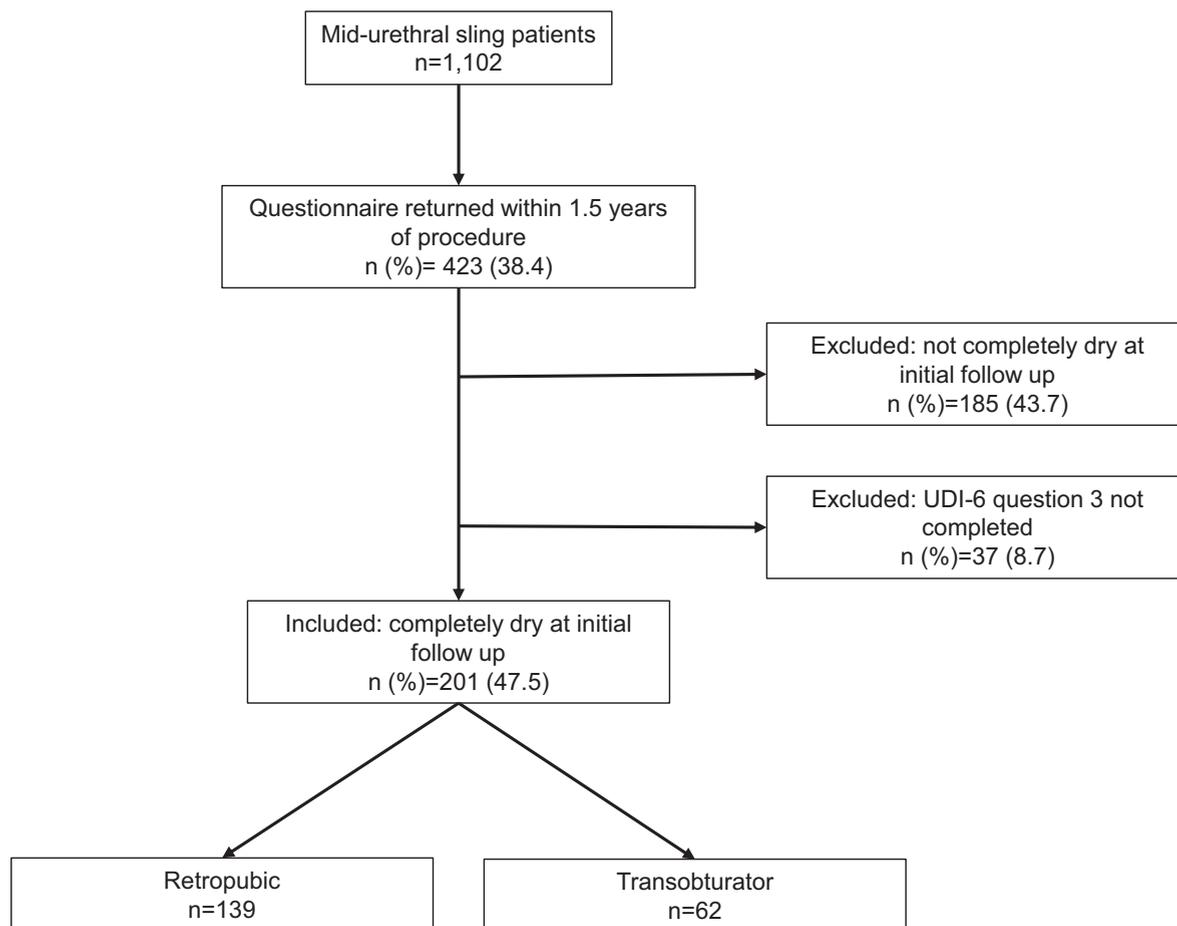
## RESULTS

Between January 19, 2001 and March 30, 2016, a total of 1102 patients had a MUS performed by 1 of four pelvic floor urologic surgeons at our institution. All RMUS were performed “top down,” and all TMUS were performed “out in.” Of these patients, 423 (293 RMUS, 130 TMUS), or 38%, were identified who had returned at least 1 questionnaire completed within the 1.5 year follow-up period. At their first follow-up questionnaire, 47% (139/293) of RMUS and 48% (62/130) of TMUS patients reported being completely dry (Fig. 1).

Demographic analysis (Table 1) showed that the mean age of our cohort was 55.8 years in the RMUS group and 58.8 years in the TMUS group. Obesity rates (BMI > 30) were 72% and 69% in the RMUS and TMUS groups, respectively. Our cohort was predominantly white (83%) and 69% of patients were nonsmoking. Of the total study population, 95% underwent UDS (94% of RMUS patients and 97% of TMUS patients). Of these patients, 92% did not demonstrate urodynamic DO (93% RMUS, 90% TMUS) and 22% did not demonstrate urodynamic SUI (19% RMUS, 18% TMUS). Additionally, 50% of RMUS and 40% of TMUS subjects had 1 or more concomitant procedures performed with the MUS. In the RMUS group 69 patients underwent 97 concomitant procedures, with the most common being cystocele repair, followed by rectocele repair and vaginal hysterectomy. In the TMUS group 25 patients had 44 concomitant procedures, with the most common being cystocele repair, vault suspension, vaginal hysterectomy, and rectocele repair.

Figure 2 presents Kaplan-Meier curves for being completely dry over time, which were censored when less than 10 patients remained in each group (at 12 years for RMUS and 5 years for TMUS). In the RMUS group, probabilities (95% confidence intervals,  $n$  = number at risk) of being completely dry at years 3, 5, and 10 were estimated at 72% (64%-81%,  $n$  = 70), 60% (51%-70%,  $n$  = 51), and 26% (18%-39%,  $n$  = 17), respectively. For TMUS, 3 and 5 year estimates were 74% (62%-88%,  $n$  = 27), and 50% (35%-70%,  $n$  = 14), respectively.

A univariate Cox proportional hazard model (Table 2) revealed that obesity ( $P$  = .003, Hazard ratio = 2.22) and increased age ( $P$  < .001, Hazard ratio = 1.043) were associated with a decreased probability of being completely dry over time in patients undergoing RMUS. No factors were significantly associated with decreased probability of being completely dry over time in patients who underwent TMUS. In the evaluation of whether there was UUI present at the time of sling failure we found that in the



**Figure 1.** Flow diagram of patients in the study.

**Table 1.** Demographic analysis of the study cohort

	RMUS	TMUS
Age, y, mean (SD)	55.8 (12.7)	58.8 (11.2)
Gravidity, median (IQR)	3 (2,3)	2 (2,4)
Parity, median (IQR)	2 (2,3)	2 (2,3)
BMI, kg/m <sup>2</sup> , mean (SD)	27.7 (5.1)	28.1 (5.8)
VLPP, cm H <sub>2</sub> O, median (IQR)	64 (50,80)	67 (56,83)
Concomitant procedures, n (%)	69 (23)	25 (19)
Prior SUI surgery, n (%)	14 (10)	2 (3)
Race n (%)		
White	82 (82)	44 (86)
Non-white	18 (18)	7 (14)
Ethnicity		
Non-Hispanic	73 (99)	40 (93)
Hispanic	1 (1)	3 (7)
Smoking history		
No	80 (63)	42 (82)
Yes	47 (37)	9 (18)
Urodynamic SUI		
No	25 (19)	17 (18)
Yes	105 (81)	43 (72)
Urodynamic DO		
No	121 (93)	54 (90)
Yes	9 (7)	6 (10)

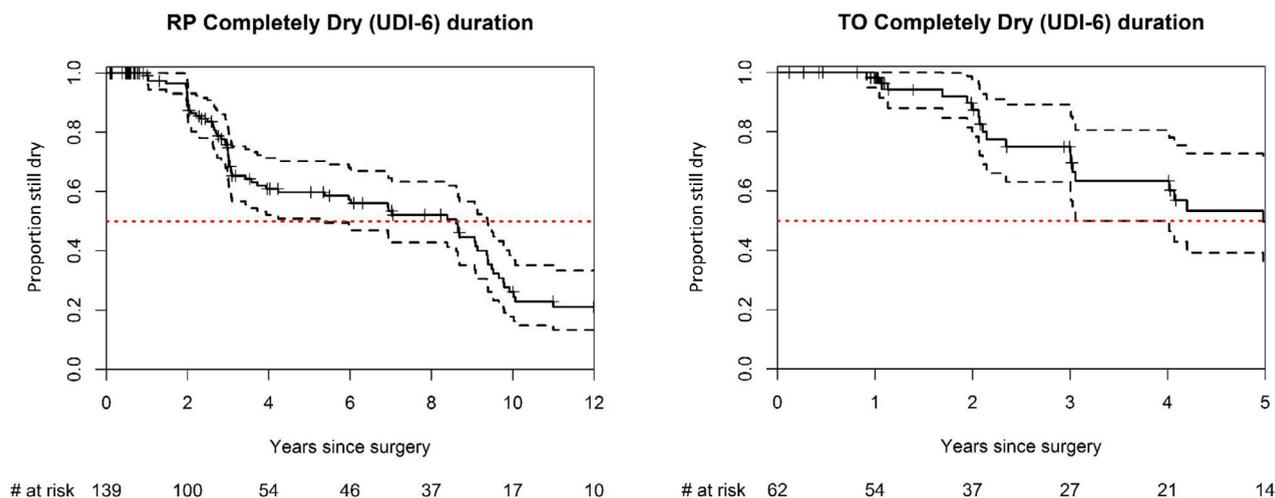
RMUS, retropubic mid-urethral slings; TMUS, transobturator mid-urethral slings; VLPP, valsalva leak point pressure, defined as the vesical pressure at the time of leakage.

RMUS group, 72% of patients (47/65) with MUS failure reported UUI, while 57% (41/72) of the patients who remained dry from SUI had UUI. In the TMUS group, 75% of patients (21/28) with MUS failure reported UUI and 36% (12/33) of patients who remained dry from SUI had UUI ([Supplementary Table 1](#)).

## DISCUSSION

Our overall reported dry rates in the first 1.5 years following MUS were 47% for RMUS and 48% for TMUS. While these percentages are lower than what has been previously reported in the literature, we believe that our patient population differs from that seen in controlled trials. For example, the Trial of Mid-urethral Slings (TOMUS) used a subjective definition of success similar to ours, in that patients had to report the absence of SUI symptoms on the MESA questionnaire. Success rates in this trial at 1 year were higher than in our series; 62% for RMUS and 56% for TMUS. However, RMUS and TMUS patients in the TOMUS trial had a preoperative VLPP of 114 cm H<sub>2</sub>O and 124 cm H<sub>2</sub>O, respectively. This is nearly double the VLPP seen in our patients (64 cm H<sub>2</sub>O for RMUS and 67 cm H<sub>2</sub>O for TMUS).<sup>11</sup>

The durability analysis reveals that if patients are initially dry after MUS surgery, 60% remained dry at 5 years for RMUS and 50% remained dry at 5 years for TMUS.



**Figure 2.** Kaplan-Meier durability plots with 95% confidence intervals for retropubic (RMUS) and transobturator (TMUS) mid-urethral slings.

While TMUS had slightly lower dry rates than RMUS in the 5-year durability analysis, we recognize that the 2 groups cannot be directly compared because the treatments were not randomized. The purpose of this study was not to make a comparison between the 2 slings, but to provide a reasonable benchmark that can be utilized for setting patient expectations during preoperative and postoperative counseling. Our data underscores that for our population, one can predict at least a 50% chance of remaining completely dry at 5 years if the patient is initially dry after MUS. In the 5-year longitudinal follow-up of TOMUS, success rates dropped to 51% for RMUS and 43% for TMUS. Although these are similar to our results, the TOMUS follow-up study included all available patients who had not undergone retreatment.<sup>12</sup>

The risk factors for MUS failure remain controversial in the literature. While some studies have found that obesity and BMI had no effect on RMUS success,<sup>13,14</sup> Bohlin et al found that BMI and smoking status were risk factors for

failure.<sup>15</sup> Our study found that obesity (BMI > 30) and age negatively affected whether patients remained dry in the RMUS group (Table 2). There were no risk factors identified as being statistically significant in the TMUS group, likely due to the smaller sample size. It is important to note that in the context of these studies, statistical significance should not be mistaken for clinical significance. In our study, the age-related hazard ratio is estimated to be 1.043 per year in the RMUS group, an effect that many practitioners may consider clinically insignificant (for small changes in age) in comparison to the benefits that RMUS slings offer. Interestingly, preoperative UDS variables, such as the presence of urodynamic DO or SUI, or a very low VLPP (<30 cm H<sub>2</sub>O) did not appear to be associated with remaining dry over time. This is in contrast to a previous study in which a VLPP of less than 86cm H<sub>2</sub>O was associated with a 2-fold increased odds of sling failure.<sup>16</sup>

This study has some limitations. Patients were asked by questionnaire to report all subsequent surgeries after their

**Table 2.** Risk of MUS failure by demographic and urodynamic variables. All urodynamic variables were measured preoperatively

	R MUS				T MUS			
	<i>n</i>	HR	CI	<i>P</i>	<i>n</i>	HR	CI	<i>P</i>
Age (per y)	139	1.043	[1.020, 1.067]	<0.001*	62	1.018	[0.984, 1.053]	0.303
Gravidity (per unit)	99	1.079	[0.877, 1.329]	0.472	50	0.968	[0.718, 1.306]	0.832
Parity (per unit)	109	1.038	[0.806, 1.338]	0.771	53	1.188	[0.869, 1.625]	0.279
†BMI (per unit)	127	1.038	[0.996, 1.082]	0.075	61	1.008	[0.938, 1.083]	0.830
VLPP (per mL)	103	0.999	[0.990, 1.008]	0.818	41	0.993	[0.973, 1.013]	0.503
Race: Non-white	100	0.884	[0.377, 2.073]	0.777	51	1.756	[0.629, 4.899]	0.282
Smoking History	127	1.082	[0.639, 1.834]	0.769	51	1.021	[0.328, 3.173]	0.972
Urodynamic SUI	130	1.807	[0.824, 3.965]	0.140	60	0.707	[0.300, 1.668]	0.428
Urodynamic DO	130	1.901	[0.813, 4.441]	0.138	60	1.149	[0.260, 5.073]	0.855
†Obesity	127	2.222	[1.314, 3.757]	0.003*	61	0.924	[0.394, 2.169]	0.856
VLPP < 70 cm H <sub>2</sub> O	103	1.153	[0.683, 1.947]	0.594	41	1.506	[0.568, 3.990]	0.410
VLPP < 30 cm H <sub>2</sub> O	103	1.264	[0.541, 2.951]	0.588	NA			

HR, hazard ratio.

\* statistically significant.

† BMI measured prior to surgery.

initial MUS, however it is possible we were not able to capture all surgeries conducted outside of our institution. Potential confounding factors, such as concomitant prolapse repair, and the presence of UUI were not assessed. The response rate to the initial surveys was low and assessment of nonresponders was not within the scope of the study. Therefore, respondents may not be representative of our entire MUS population, and characteristics of the nonrespondent population cannot be determined. The data was analyzed in a retrospective, rather than prospective manner. We defined completely dry as patients who were “not at all” bothered by SUI symptoms postprocedure. We acknowledge that there is an inherent problem with this definition, as the UDI-6 assesses bother from symptoms rather than the absence of the symptoms themselves, and the way it is written can be confusing for patients. However, given that the MUS is a surgery that is performed only for bothersome symptoms,<sup>17</sup> “bother” is the most important measure in assessing whether a patient is dry. Additionally, we did not analyze data from the 185 patients who underwent MUS, but were not completely dry at initial follow-up. However, the focus of this study was on dry rates over time, as reported through patient responses to UDI-6 question 3, focusing our conclusions to only this aspect of the patient experience. Future studies should explore whether there were any clinical or demographic differences between patients who were completely dry at initial follow-up as compared to those who were not, as well as different definitions of success over time.

Despite these limitations this study demonstrates the chances of being completely dry, initially and over time, after RMUS or TMUS in a real-world clinical setting. Urologists in particular may find this data useful considering that much of the data on MUS comes from gynecology literature. Because it has been suggested that urologists tend to perform MUS surgeries on more complicated patients, those studies may not reflect the results seen in a typical urology practice.<sup>8</sup> In addition, the results from this study demonstrate a completely dry rate that is less than that shown in randomized controlled trials, likely due to the lack of patient selection in our study population. For this reason, although randomized controlled trials represent the highest level of evidence, clinicians may find the data in this study to be more similar to that seen in their own practice.

## CONCLUSION

This study examines the probability of being completely dry over time after RMUS and TMUS in a real-world clinical setting that may be useful for patient counseling in urology clinics. Based on our results patients who were completely dry at 1.5 years after MUS can be counseled that they have at least 50% probability of remaining dry for 8 years after RMUS and 5 years after TMUS.

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## SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found in the online version at <https://doi.org/10.1016/j.urology.2018.12.036>.

## References

1. Minassian VA, Drutz HP, Al-Badr A. Urinary incontinence as a worldwide problem. *Int J Gynaecol Obstet.* 2003;82:327–338.
2. Subak LL, Brown JS, Kraus SR, et al. The “costs” of urinary incontinence for women. *Obstet Gynecol.* 2006;107:908–916.
3. Chong EC, Khan AA, Anger JT. The financial burden of stress urinary incontinence among women in the United States. *Curr Urol Rep.* 2011;12:358–362.
4. Wai CY, Curto TM, Zyczynski HM, et al. Patient satisfaction after mid-urethral sling surgery for stress urinary incontinence. *Obstet Gynecol.* 2013;121:1009–1116.
5. Foss Hansen M, Lose G, Kesmodel US, et al. Reoperation for urinary incontinence: a nationwide cohort study, 1998–2007. *Am J Obstet Gynecol.* 2016;214. 263 e1–263 e8.
6. Wu MP, Long CY, Liang CC, et al. Trends in reoperation for female stress urinary incontinence: a nationwide study. *Neurourol Urodyn.* 2015;34:693–698.
7. Ford AA, Rogerson L, Cody JD, et al. Mid-urethral sling operations for stress urinary incontinence in women. *Cochrane Database Syst Rev.* 2017;7 CD006375.
8. James MB, Theofanides MC, Sui W, et al. Sling procedures for the treatment of stress urinary incontinence: comparison of national practice patterns between urologists and gynecologists. *J Urol.* 2017;198:1386–1391.
9. Uebersax JS, Wyman JF, Shumaker SA, et al. Short forms to assess life quality and symptom distress for urinary incontinence in women: the Incontinence Impact Questionnaire and the Urogenital Distress Inventory. Continence Program for Women Research Group. *Neurourol Urodyn.* 1995;14:131–139.
10. R Core Team (2016). R: A Language And Environment For Statistical Computing. *R Foundation for Statistical Computing*, V., Austria. URL <http://www.R-project.org/>
11. Richter HE, Albo ME, Zyczynski HM, et al. Retropubic versus transobturator mid-urethral slings for stress incontinence. *NEJM.* 2010;362:p2066–p2076.
12. Kenton K, Stoddard AM, Zyczynski H, et al. 5-year longitudinal follow-up after retropubic and transobturator mid-urethral slings. *J Urol.* 2015;193:203–210.
13. Pereira I, Valentim-Lourenco A, Castro C, et al. Incontinence surgery in obese women: comparative analysis of short- and long-term outcomes with a transobturator sling. *Int Urogynecol J.* 2016;27:247–253.
14. Jeong SJ, Lee HS, Lee JK, et al. The long-term influence of body mass index on the success rate of mid-urethral sling surgery among women with stress urinary incontinence or stress-predominant mixed incontinence: comparisons between retropubic and transobturator approaches. *PLoS One.* 2014;9 e113517.
15. Bohlin KS, Ankardal M, Pedroletti C, et al. The influence of the modifiable life-style factors body mass index and smoking on the outcome of mid-urethral sling procedures for female urinary incontinence. *Int Urogynecol J.* 2015;26:343–351.
16. Nager CW, Sirls L, Litman HJ, et al. Baseline urodynamic predictors of treatment failure 1 year after mid urethral sling surgery. *J Urol.* 2011;186:597–603.
17. Kobashi KC, Albo ME, Dmochowski RR, et al. Surgical treatment of female stress urinary incontinence: AUA/SUFU guideline. *J Urol.* 2017;198:875–883.