

5-Year Continence Rates, Satisfaction and Adverse Events of Burch Urethropexy and Fascial Sling Surgery for Urinary Incontinence

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Abbreviations and Acronyms

IIQ = Incontinence Impact Questionnaire

SUI = stress urinary incontinence

UDI = Urogenital Distress Inventory

UI = urinary incontinence

UUI = urinary urgency incontinence

Purpose: We characterized continence, satisfaction and adverse events in women at least 5 years after Burch urethropexy or fascial sling with longitudinal followup of randomized clinical trial participants.

Materials and Methods: Of 655 women who participated in a randomized surgical trial comparing the efficacy of the Burch and sling treatments 482 (73.6%) enrolled in this long-term observational study. Urinary continence status was assessed yearly for a minimum of 5 years postoperatively. Continence was defined as no urinary leakage on a 3-day voiding diary, and no self-reported stress incontinence symptoms and no stress incontinence surgical re-treatment.

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Clinical Trial Registration NCT00064662 (www.clinicaltrials.gov).

Study received institutional review board approval.

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Results: Incontinent participants were more likely to enroll in the followup study than continent patients (85.5% vs 52.2%) regardless of surgical group ($p < 0.0001$). Overall the continence rates were lower in the Burch urethropexy group than in the fascial sling group ($p = 0.002$). The continence rates at 5 years were 24.1% (95% CI 18.5 to 29.7) vs 30.8% (95% CI 24.7 to 36.9), respectively. Satisfaction at 5 years was related to continence status and was higher in women undergoing sling surgery (83% vs 73%, $p = 0.04$). Satisfaction decreased with time ($p = 0.001$) and remained higher in the sling group ($p = 0.03$). The 2 groups had similar adverse event rates (Burch 10% vs sling 9%) and similar numbers of participants with adverse events (Burch 23 vs sling 22).

Conclusions: Continence rates in both groups decreased substantially during 5 years, yet most women reported satisfaction with their continence status. Satisfaction was higher in continent women and in those who underwent fascial sling surgery, despite the voiding dysfunction associated with this procedure.

Key Words: treatment outcome; urinary incontinence, stress; longitudinal studies

An ideal goal of surgery for stress urinary incontinence is the achievement of long-term continence and low rates of complications. Currently preoperative counseling of women planning SUI surgery is based on studies with limited followup, while surgeons and patients alike would be better served by realistic long-term consequences of the procedure, including continence. Thus, there is an important need for a better characterization of a wide range of outcomes related to SUI surgery during an extended period.

The 2011 Cochrane review for traditional suburethral slings was limited by the availability of studies of generally short followup ranging from 6 to 24 months.¹ However, current evidence suggests that women who undergo Burch urethropexy can expect overall cure rates of 69% to 88% with a failure rate of 15% to 20% in the first 5 years after surgery.^{2,3} A second meta-analysis of 39 studies on SUI surgery concluded that the long-term effects of this surgery could not be adequately assessed because of the short followup in many studies, and differences in outcome measures and analytic techniques to deal with subjects lost to followup.⁴

Although mid urethral slings are currently the most commonly used SUI surgical procedures, the Burch urethropexy and pubovaginal fascial sling procedures have been studied extensively. We previously reported the 2-year results of the SISTER (Stress Incontinence Surgical Treatment Efficacy Trial), a randomized controlled trial of the Burch urethropexy and the pubovaginal fascial sling.^{5,6} Recruitment of this cohort of women provided an opportunity to study the long-term effects of SUI surgery. After women enrolled in the SISTER trial completed that study, they were invited to enroll in a prospective observational study, the E-SISTER (Extended SISTER). We report the continence status, frequency of adverse events and self-reported satisfaction of women enrolled in E-SISTER a minimum of 5 years after their randomized surgery.

MATERIALS AND METHODS

The design and primary outcome of the SISTER trial have been published previously.^{5,6} Women who completed the clinical trial (assessment of the primary outcome at 2 years after surgery) were eligible for the prospective observational study. The observational study was approved by the institutional review board of all participating institutions. All study participants provided written informed consent.

Participation included a combination of telephone and mail contact every 6 months starting at postoperative month 30. The primary outcome of continence status was defined by a composite measure consisting of no symptoms of urinary incontinence on a 3-day voiding diary as well as no self-reported stress urinary incontinence symptoms on the MESA (Medical, Epidemiologic, and Social Aspects of Aging Project) questionnaire (response of rarely or never for each stress-type symptom) and no surgical re-treatment for SUI. Continence was estimated conservatively, as when 1 or more of the individual components of the outcome was missing but another measure was positive (incontinence), then the woman was considered incontinent. When 1 or more measures were missing and all other measures indicated continence, the participant was treated as missing and the subject was not considered continent. Other validated questionnaires assessing lower urinary tract symptom distress and impact included the UDI and IIQ.⁷

Self-reported treatment satisfaction was assessed with the question, "How satisfied or dissatisfied are you with the result of bladder surgery related to the following symptoms. . . ." with response options of completely dissatisfied, mostly dissatisfied, neutral, mostly satisfied and completely satisfied. Study participants were also queried over the telephone every 6 months as surveillance for additional SUI treatment including other SUI surgery, tightening of the randomized incontinence sling and collagen injections. Surveillance was also performed to inquire about treatment for persistent or de novo UUI, urinary retention, prolapse and adverse events. Adverse events were categorized by organ system and assigned a severity code according to a modified version of the classification system developed by Dindo et al.⁸

Statistical Methods

Baseline characteristics were compared between the 2 surgical groups using a 2-sample t test for continuous

variables and chi-square test for categorical variables. The unadjusted continence rates in the 2 groups at 5 years were compared using Fisher's exact test. Repeated measures logistic regression models were used to analyze change in treatment satisfaction with time. Available data up to 7 years are shown. All analyses were performed with SAS® statistical software version 9.2.

RESULTS

Of the 655 women randomized into SISTER 482 (73.6%) were enrolled into E-SISTER. Figure 1 presents patient enrollment and followup for the clinical trial and the current prospective observational study. There were no clinically important differences between surgical groups (Burch 239, sling 243) in demographic and clinical characteristics at enrollment into SISTER (table 1). Overall, participants were approximately 53 years old, predominantly white, parous and overweight. Only a minority of patients reported prior incontinence surgery (15%) or were found to have pelvic organ prolapse (Pelvic Organ Prolapse Quantitation system stage III/IV, 17%) during baseline assessment for the SISTER clinical trial.

E-SISTER participants were older (mean age 53 vs 49 years, $p = 0.0001$) and a higher proportion had at least a college education (29% vs 14%, $p = 0.005$) than SISTER participants who did not enroll. How-

ever, women who were incontinent 24 months after randomized surgery were more likely to enroll in E-SISTER (85.5%) than those who were continent (52.2%), regardless of assigned surgical group ($p < 0.0001$).

The Kaplan-Meier cumulative survival curves for continence rates are significantly different for the Burch urethropexy and fascial sling groups (log rank test [chi-square 10.12] $p = 0.002$) as displayed in figure 2. The continence rates were lower in the Burch urethropexy group than in the fascial sling group as evidenced by the rates at 5 years of 24.1% (95% CI 18.5 to 29.7) vs 30.8% (95% CI 24.7 to 36.9), respectively.

The proportion of continent women by overall composite outcome criteria and by each component of the composite end point are represented in figure 3. Although there was not a clinically or statistically significant important difference in continence status between surgical groups from the 3-day voiding diary, a significantly greater proportion of women in the sling group were continent by self-report on the MESA questionnaire (42% vs 31%, $p = 0.02$). Fewer women in the fascial sling group experienced surgical re-treatment compared to women in the Burch urethropexy group (2% vs 12%, $p < 0.0001$).

Interestingly there were no significant differences between the Burch urethropexy and fascial sling groups with regard to lower urinary tract symptom distress at 5 years after surgery as measured by UDI scores (50.2 ± 50.9 vs 40.2 ± 45.8 , respectively, $p = 0.05$) nor quality of life as measured by IIQ scores (43.1 ± 68.2 vs 44.8 ± 79.6 , respectively, $p = 0.83$).

Table 2 displays self-reported treatment satisfaction by randomized surgery group overall and by continence status. A significantly greater proportion of women in the fascial sling group than in the Burch urethropexy group reported satisfaction with their continence status at 5 years (83% vs 73%, $p = 0.04$). Treatment satisfaction differed by continence status. Almost all continent participants were satisfied (Burch 100% and sling 97%) in contrast to incontinent women who had a satisfaction rate of 65% for Burch and 75% for sling. As shown in figure 4 the proportion of women who remained satisfied with treatment decreased slightly from 24 months to 5 years, ie 79% to 73% in the Burch group and 87% to 83% in the sling group. Results of the repeated measures logistic regression models indicated that the change in satisfaction with time was statistically significant ($p = 0.001$) and that satisfaction among participants who underwent Burch was significantly lower than for those treated with the sling ($p = 0.03$). However, the trends over time did not differ significantly between the 2 treatments ($p = 0.48$).

Treatment for voiding dysfunction was required more frequently in the fascial sling group while treatment for prolapse and urge incontinence oc-

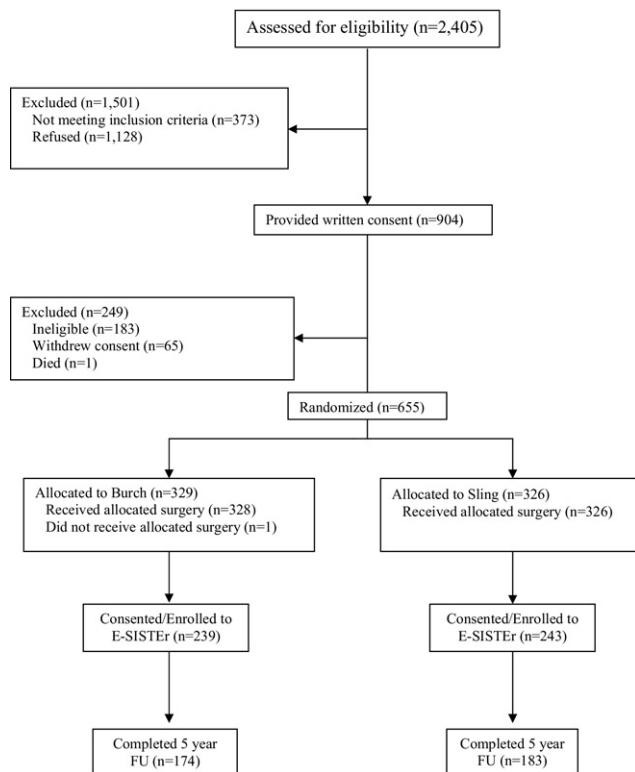


Figure 1. Flow of subjects through SISTER and E-SISTER. FU, followup.

Table 1. Selected baseline characteristics of E-SISTER subjects by randomization group

	Burch		Sling		p Value
<i>Demographic characteristics</i>					
Mean pt age (SD)	53.3 (10.5)		52.3 (9.7)		0.31
No. racial and ethnicity group (%):*					0.03
Hispanic	18	(8)	30	(12)	
NonHispanic white	186	(78)	179	(73)	
NonHispanic black	9	(4)	19	(8)	
NonHispanic other	25	(10)	15	(6)	
No. marital status (%):					0.38
Not married	68	(28)	78	(32)	
Married/living as married	171	(72)	165	(68)	
No. education (%):					0.90
High school or less	75	(31)	80	(33)	
Some training after high school	95	(40)	92	(38)	
Baccalaureate or more	69	(29)	71	(29)	
No. household income (%):					0.91
Less than \$20,000	41	(19)	39	(17)	
\$20,000–\$49,999	64	(30)	67	(29)	
\$50,000–\$79,999	45	(21)	50	(22)	
\$80,000+	63	(30)	73	(32)	
<i>Risk factors for UI</i>					
Mean kg/m ² body mass index (SD)	29.7 (6.3)		29.9 (5.6)		0.69
No. vaginal deliveries (%):					0.19
0	21	(9)	26	(11)	
1–2	112	(47)	94	(39)	
3+	106	(44)	123	(51)	
No. prior UI surgery (before SISTER) (%):					0.65
No	201	(84)	208	(86)	
Yes	38	(16)	35	(14)	
No. prolapse (%):					0.80
Stage 0/1	53	(22)	48	(20)	
Stage 2	1,476	(61)	152	(62)	
Stage 3/4	40	(17)	43	(18)	
<i>Quality of life</i>					
Mean total UDI score (SD)	151.5 (49.4)		149.4 (46.1)		0.62
Mean total IIQ score (SD)	172.1 (102.8)		162.8 (98.3)		0.31
<i>Clinical characteristics</i>					
Mean incontinence episodes/day (SD)	3.3 (3.3)		3.0 (2.7)		0.29
Mean UI symptom index (SD):†					
Stress	71.7	(16.7)	70.5	(17.2)	0.41
Urge	36.9	(21.6)	35.5	(21.5)	0.46
Mean degrees Q-tip test angle (SD):					
Resting	15.9	(16.8)	14.8	(17.9)	0.50
Straining	61.1	(19.2)	59.7	(17.1)	0.39
Delta = straining–resting	45.3	(18.8)	44.9	(18.2)	0.83
No. any medication for UUI or SUI (%):					0.21
No	183	(77)	174	(72)	
Yes	56	(23)	69	(28)	
<i>Urodynamics measures</i>					
No. presence of urodynamic stress incontinence (%):					0.72
Yes	211	(91)	215	(90)	
No	22	(9)	25	(10)	
Mean Valsalva leak point pressure (SD)	114.8 (39.0)		120.4 (36.2)		0.21
Mean delta Valsalva leak point pressure (SD)	78.5 (38.6)		84.08 (33.8)		0.19
No. detrusor overactivity (%)	25 (11)		16 (7)		0.11

* Self-reported.

† As measured by the MESA questionnaire.

curred with similar frequency in the 2 groups (table 3). No serious adverse events were reported in E-SISTER. Adverse event rates were similar for the 2 treatment groups with Burch 10% and sling 9%. There were 75 adverse events (Burch 38 and sling

37) in 45 participants (Burch 23 and sling 22). Nearly all events (72/75) were recurrent urinary tract infection (36 events in 21 Burch patients, 36 events in 21 sling patients). The other 3 adverse events occurred in 3 different women including 1

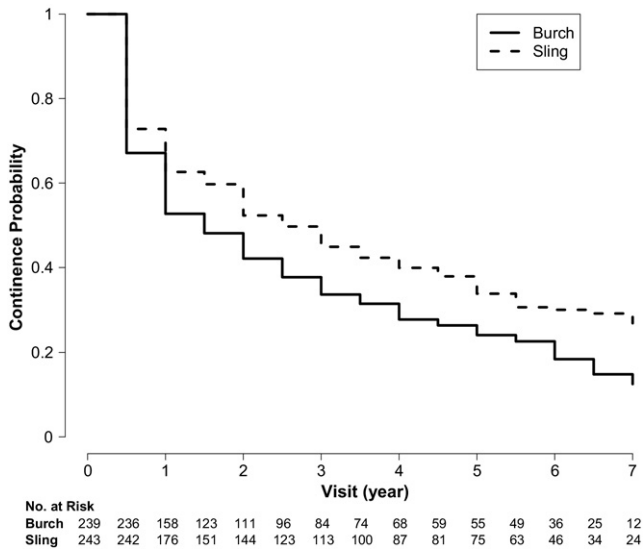


Figure 2. Continenence rates over time

exposed suture at the vaginal apex from concomitant prolapse surgery at the time of sling, 1 sacrocolpopexy mesh erosion in a sling patient, and ongoing neuropathy with numbness in the right calf and foot in a Burch patient.

DISCUSSION

These data from well characterized, randomized trial participants who enrolled into a longitudinal observational cohort clearly demonstrate that continence rates after Burch urethropexy and fascial sling decrease steadily during the first 5 years after surgery. Although the rate of decrease was similar by surgical group, the higher initial continence rates in the fascial sling group at the onset of E-SISTER resulted in more continent women at 5 years and subsequently fewer subjects who underwent SUI re-treatment in this group.

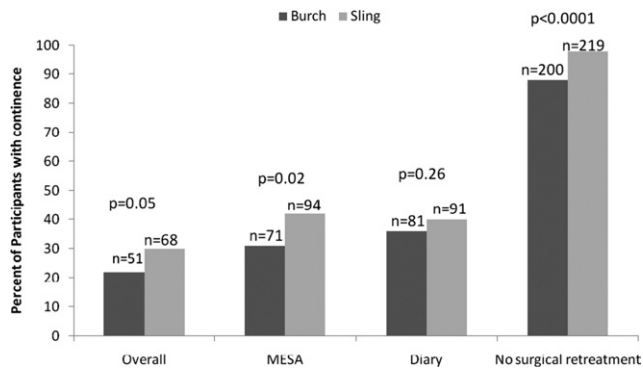


Figure 3. Proportion of patients reporting continence at 5 years by composite criteria and individual outcome components. Other therapy includes medical, device, behavior and other.

Table 2. Satisfaction at 5-year visit

	No. Burch (%)	No. Sling (%)	p Value
All E-SISTER respondents:			0.04
Satisfied	126 (73)	148 (83)	
Dissatisfied	46 (27)	31 (17)	
Excluding woman with surgical re-treatment:			0.13
Satisfied	115 (76)	145 (83)	
Dissatisfied	37 (24)	30 (17)	
Assuming those surgically re-treated were dissatisfied:		175	0.003
Satisfied	115 (67)	145 (81)	
Dissatisfied	57 (33)	34 (19)	
Stratified by overall success:*		179	
Continenence:			0.51
Satisfied	42 (100)	57 (97)	
Dissatisfied	0 (0)	2 (3)	
Incontinence:			0.10
Satisfied	84 (65)	88 (75)	
Dissatisfied	45 (35)	29 (25)	

* Overall success was evaluated on or before 5 years: Women lost to followup and without continence status were excluded from analysis.

The proportion of continent women in this study at 5 years is lower than that reported in previous studies. Ward et al reported a 5-year continence rate (based on a negative 1-hour pad test with less than 1 gm increase in weight) of 46% of women randomized to Burch colposuspension and 39% of those randomized to tension-free vaginal tape.⁹ Jelovsek et al reported incontinence rates 4 to 8 years after randomization to tension-free vaginal tape (48%) or laparoscopic Burch (58%).¹⁰ In that study subjects were characterized as continent by a never response to the Incontinence Severity Index question, “How often do you experience urine leakage?” Therefore, it is difficult to compare studies given the variation in outcome measures and definitions of continence. The lower continence rates observed in E-SISTER are likely related to our use of a composite, unidi-

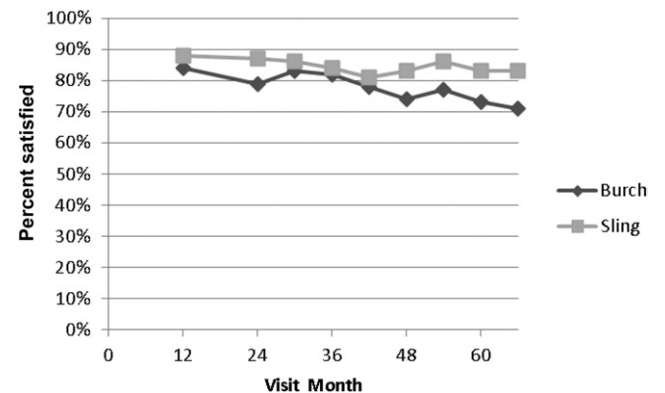


Figure 4. Percentage of women who reported being satisfied with their urine leakage after surgery

Table 3. Patients requiring treatment for voiding dysfunction, urge incontinence or prolapse

	No. Unique Burch	No. Unique Sling
De novo UUI	7	3
Persistent UUI	29	33
Prolapse	5	1
Voiding dysfunction:*	1	7
Catheter	1	6
Surgery	0	4
Other†	1	3

* Subcategories under voiding dysfunction represent types of treatment received.

A woman could receive more than 1 treatment.

† Includes medical, device, behavior etc.

rectional definition of continence. We and others have shown that composite end points are associated with lower continence rates.⁶ The traditional elements in the composite end points do not allow for meaningful clinical improvement in symptoms. In addition, the unidirectional “once a failure, always a failure” categorization of continence status is not consistent with current epidemiological evidence suggesting that continence status can fluctuate.¹¹

There is likely variation in continence status that depends on patient factors such as level of physical activity or severity of other medical conditions. It is well-known that UUI is common in women with stress urinary incontinence, and in fact, most SISTER participants reported some level of urgency and/or urge incontinence at baseline.¹² Although stress incontinence surgery is not considered a treatment for UUI, many of the outcome measures used to define surgical success do not differentiate between stress and urge incontinent episodes. Thus, a patient with persistent urge incontinence would still be considered incontinent despite the resolution of stress incontinence. A significant number of patients, 16%, in both surgical groups, required treatment for urge incontinence in the E-SISTER trial. This number may not reflect all patients with postoperative incontinence since some may not have sought treatment.

Despite the decrease in the proportion of continent women during 5 years, patient satisfaction rates were relatively stable compared to the 2-year primary outcome point (fascial sling 86% vs Burch urethropexy 78%).⁶ The disparity between satisfaction and decreasing continence rates has been reported in other studies, and may be due to outcome measures that do not capture success from the patient perspective as 63% of women categorized as incontinent were satisfied with their continence status at 5 years.¹³ We found that multiple self-assessment measures of incontinence, including measures of symptom distress and impact, remained markedly improved from baseline despite a statistically significant deterioration of continence rates during the

study period. These improvements are likely contributors to the notable satisfaction rates in both groups despite the decreasing continence status.

In addition to factors specific to the individual surgical procedures and the definitional limitations for the primary outcome, long-term continence rates are also influenced by the natural history of the continence mechanism with aging. Epidemiological data clearly demonstrate that the likelihood of incontinence increases with age. However, we cannot comment on whether the SUI surgeries reduce the proportion of incontinent women compared to a similar cohort of women who did not undergo SUI surgery.

We found that incontinent SISTER participants were more likely to participate in the E-SISTER study, thus biasing the sample toward incontinence over time. It is often assumed that patients with failed procedures seek care elsewhere and, therefore, are less likely to participate in followup studies. However, our experience suggests otherwise and may be related to the high level of treatment satisfaction at 2 years or other uncharacterized aspects of the physician-patient relationship. The data in this report are not directly comparable to that of the SISTER primary outcome report as the composite outcome in this longitudinal study did not include an objective bladder fill stress test or a 24-hour pad test, which may have further decreased continence rates.⁶

There were no differences in serious adverse event or adverse event rates between the 2 surgical groups in the 5-year period after the index study surgery, and adverse events were largely related to cystitis. Voiding dysfunction continued to occur in this period almost exclusively in the sling group, presumably related to new or continuing UUI.

This cohort of randomized women who participated in the E-SISTER study provided high quality information about the patient’s experience with continence 5 years after surgery for stress incontinence. The results of this study are robust due to the well-defined surgical cohort, followed closely at multiple centers across the country, and assessed by a standardized and validated set of measures. Surgical treatments have evolved since this study was designed and implemented. Nonetheless, the findings presented here provide benchmark continence rates using multidimensional/multicomponent outcomes for long-term efficacy comparisons of other surgical techniques such as mid urethral slings.

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