Supplementary Online Content

Sung VW, Borellow France D, Newman DK, et al; NICHD Pelvic Floor Disorders Network. Effect of behavioral and pelvic floor muscle therapy combined with surgery vs surgery alone on incontinence symptoms among women with mixed urinary incontinence: the ESTEEM randomized clinical trial. *JAMA*. doi:10.1001/jama.2019.12467

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This supplementary material has been provided by the authors to give readers additional information about their work.

eMethods: Estimation of minimal clinical important differences for the Urogenital Distress Inventory in the ESTEEM population

Minimal important differences for the Urogenital Distress Inventory (UDI) were estimated in the trial's study population using distribution (both one-half SD and standard error of measurement) and anchor-based methods. The Pateint-Global Impression of Improvement (PGI-I), the Patient Global Impression Satisfaction (PGI-S), the Incontinence Impact Questionnaire (IIQ) and incontinence episodes on diary were considered as potential anchors. Due to the relatively low number of women who requested additional treatment, this outcome was not assessed as a potential anchor. The IIQ was assessed as an anchor as an alternative measure of participant-reported incontinence impact. The target sample size provided 90% power to detect a difference as small as 19 points, and 80% power to detect a difference of 16.5 points in UDI-total score between treatment groups.

eTable 1. Other Baseline Characteristics of Eligible and Randomized Participants.

Characteristic	*Category*	*Combined Group (N=235)*	*Sling only Group (N=229)*	*P-value*
Insurance, No. (%)	Private/HMO	163 (69.4)	163 (71.2)	0.67
	Medicaid/Medicare	83 (35.3)	71 (31.0)	0.32
	Self-pay	1 (0.4)	0 (0.0)	0.32
	Other	22 (9.4)	14 (6.1)	0.19
Coffee with caffeine, No. (%)	None or less than 1/mo	74 (31.5)	60 (26.5)	0.62
	1-3/mo	7 (3.0)	14 (6.2)	
	1/wk	5 (2.1)	5 (2.2)	
	2-4/wk	8 (3.4)	6 (2.7)	
	5-6/wk	4 (1.7)	7 (3.1)	
	1/day	72 (30.6)	67 (29.6)	
	2-3/day	57 (24.3)	56 (24.8)	
	4-5/day	5 (2.1)	9 (4.0)	
	6+/day	3 (1.3)	2 (0.9)	
Tea with caffeine, No. (%)	None or less than 1/mo	132 (56.2)	138 (61.1)	0.63
	1-3/mo	29 (12.3)	21 (9.3)	
	1/wk	13 (5.5)	11 (4.9)	
	2-4/wk	15 (6.4)	20 (8.8)	
	5-6/wk	2 (0.9)	4 (1.8)	
	1/day	29 (12.3)	17 (7.5)	
	2-3/day	11 (4.7)	10 (4.4)	
	4-5/day	2 (0.9)	3 (1.3)	
	6+/day	2 (0.9)	2 (0.9)	

Characteristic	*Category*	*Combined Group (N=235)*	*Sling only Group (N=229)*	*P-value*
Caffeinated soda, No. (%)	None or less than 1/mo	118 (50.2)	108 (47.8)	0.83
	1-3/mo	37 (15.7)	34 (15.0)	
	1/wk	18 (7.7)	14 (6.2)	
	2-4/wk	20 (8.5)	19 (8.4)	
	5-6/wk	3 (1.3)	2 (0.9)	
	1/day	22 (9.4)	22 (9.7)	
	2-3/day	11 (4.7)	21 (9.3)	
	4-5/day	2 (0.9)	2 (0.9)	
	6+/day	4 (1.7)	4 (1.8)	
Chocolate, No. (%)	None or less than 1/mo	83 (35.3)	67 (29.8)	0.16
	1-3/mo	54 (23.0)	60 (26.7)	
	1/wk	41 (17.4)	39 (17.3)	
	2-4/wk	28 (11.9)	35 (15.6)	
	5-6/wk	7 (3.0)	5 (2.2)	
	1/day	19 (8.1)	10 (4.4)	
	2-3/day	3 (1.3)	3 (1.3)	
	4-5/day	0 (0.0)	4 (1.8)	
	6+/day	0 (0.0)	2 (0.9)	
3 or more urinary tract infections in past year, No. (%)		18 (7.7)	21 (9.3)	0.53
Current urinary tract infection symptoms, No. (%)		6 (2.6)	4 (1.8)	0.56
Stress Urinary Incontinence diagnosis by positive cough stress test, No. (%)*		163 (69.4)	159 (70.0)	0.87
Stress Urinary Incontinence diagnosis by urodynamic assessment, No. (%)		224 (96.1)	209 (91.3)	0.03
Ever pregnant, No. (%)		220 (93.6)	218 (95.6)	0.34
Cesarean deliveries, median [min, max], No.		0.0 [0.0, 5.0]	0.0 [0.0, 5.0]	0.17

Characteristic	*Category*	*Combined Group (N=235)*	*Sling only Group (N=229)*	*P-value*
Currently using estrogen therapy, No. (%)	Oral/Patch	21 (8.9)	20 (8.8)	0.95
	Vaginal cream/tablets	32 (13.6)	35 (15.4)	0.59
	None	176 (74.9)	176 (77.2)	0.56
Other urinary incontinence therapies, No. (%)	Any past pelvic floor therapy or treatment	174 (74.4)	160 (69.9)	0.28
	Unsupervised training/exercise/diet	165 (70.5)	155 (67.7)	0.51
	Supervised training/exercise	22 (9.4)	23 (10.0)	0.81
	Biofeedback with behavioral therapy	6 (2.6)	13 (5.7)	0.09
	Any behavioral or pelvic floor muscle training	171 (73.1)	160 (69.9)	0.45
	Supervised behavioral or pelvic floor muscle training	24 (10.3)	28 (12.2)	0.50
	Electrical stimulation	2 (0.9)	8 (3.5)	0.05
	Posterior tibial nerve stimulation	0 (0.0)	1 (0.4)	0.31
	Continence pessary	19 (8.1)	13 (5.7)	0.30

*****Eligibility included documentation of stress urinary incontinence either on cough stress test and/or on urodynamic testing

eTable 2. Comparison of Primary Analysis and Multiple Imputation Results.

		Combined Group	*Sling Only Group*	*Combined vs Sling only*	
Outcome Type	*Months*	*Mean (SD), n/N (%), or Mean Change from Baseline (95% CI)*	*Mean (SD), n/N (%), or Mean Change from Baseline (95% CI)*	*Estimated Mean Difference or Odds Ratio (95% CI)*	*P-value*
Primary Outcome	**Urogenital Distress Inventory (UDI)-Total Score**				
	Primary Analysis				
	0	177.98 (42.78)	176.82 (40.53)		
	3	-125.65 (-143.44, -107.86)	-119.95 (-137.61, -102.29)	-5.70 (-15.84, 4.43)	0.27
	6	-126.49 (-144.17, -108.80)	-118.21 (-135.76, -100.66)	-8.27 (-18.01, 1.46)	0.10
	12	-128.15 (-146.51, -109.78)	-114.73 (-133.29, -96.18)	-13.42 (-25.87, -0.96)	0.04
	Multiple Imputation				
	0	177.98 (42.78)	176.82 (40.53)		
	3	-130.77 (-147.80, -113.74)	-122.93 (-140.02, -105.84)	-7.84 (-17.76, 2.07)	0.12
	6	-131.20 (-148.12, -114.29)	-122.01 (-138.83, -105.19)	-9.20 (-18.58, 0.18)	0.06
	12	-132.07 (-149.55, -114.59)	-120.17 (-137.79, -102.54)	-11.90 (-23.45, -0.36)	0.04

eTable 3. Primary and Secondary Outcomes Through 12 Months, Post-Hoc Sensitivity Analysis with Site as a Random Effect.[a]

	Baseline		*3 Months*			*6 Months*			*12 Months*		
Outcome Type	***Combined Group***	***Sling Only***	***Combined Group***	***Sling Only Group***	***P-value***	***Combined Group***	***Sling Only Group***	***P-value***	***Combined Group***	***Sling Only Group***	***P-value***
Urogenital Distress Inventory (UDI)-Total Score											
Score, unadjusted mean (SD)	178.0 (42.8)	176.8 (40.5)	36.4 (44.5)	38.9 (46.2)		33.2 (43.6)	42.5 (55.2)		33.8 (45.9)	40.3 (48.9)	
Difference from baseline, adjusted mean (95% CI)			-128.6 (-146.3, -110.9)	-123.0 (-140.5, -105.4)		-129.5 (-147.1, -111.9)	-121.3 (-138.7, -103.8)		-131.3 (-149.5, -113.0)	-117.9 (-136.3, -99.4)	
Difference in difference, mean (95% CI)			-5.6 (-15.7, 4.5)		0.27	-8.2 (-17.9, 1.5)		0.10	-13.4 (-25.9, -1.0)		0.03
UDI-Irritative Score											
Score, unadjusted mean (SD)	66.0 (19.6)	67.6 (19.7)	16.2 (21.1)	17.6 (22.4)		14.1 (20.0)	19.4 (26.5)		13.7 (20.4)	18.0 (23.8)	
Difference from baseline, adjusted mean (95% CI)			-43.7 (-51.9, -35.5)	-42.2 (-50.3, -34.1)		-44.5 (-52.7, -36.4)	-41.5 (-49.6, -33.4)		-46.1 (-54.6, -37.6)	-40.0 (-48.7, -31.3)	
Difference in difference, adjusted mean (95% CI)			-1.5 (-6.1, 3.1)		0.52	-3.0 (-7.5, 1.4)		0.18	-6.1 (-12.1, -0.1)		0.05
UDI-Stress Score											
Score, unadjusted mean (SD)	86.0 (17.6)	84.9 (18.0)	14.8 (22.5)	15.4 (21.9)		14.8 (22.4)	17.4 (25.8)		14.6 (23.6)	16.8 (23.8)	
Difference from baseline, adjusted mean (95% CI)			-66.9 (-75.8, -58.0)	-65.5 (-74.3, -56.6)		-67.1 (-75.9, -58.3)	-64.3 (-73.1, -55.5)		-67.6 (-76.7, -58.4)	-62.0 (-71.2, -52.8)	
Difference in difference, adjusted mean (95% CI)			-1.4 (-6.5, 3.7)		0.60	-2.8 (-7.6, 2.0)		0.26	-5.6 (-11.7, 0.5)		0.07

[a] Difference from baseline, difference in difference, and p-values are from longitudinal treatment models that were adjusted for time since baseline and interaction between treatment and time, retreatment and interactions with treatment and time, baseline incontinence severity, and that accounted for multiple observation per participant. In this post-hoc sensitivity analysis, site was included in the models as a random effect instead of a fixed effect.

eTable 4. Last Timepoint at which Each Retreated Participant was Included in Statistical Models.

Time Point[a]	*Combined Group (N=20)*	*Sling Only Group (N=36)*
Baseline	6	9
2 Weeks	1	1
3 Months	7	11
4.5 Months	0	2
6 Months	3	7
8 Months	0	1
12 Months	3	5

[a]Statistical models comparing treatments over time include outcomes from all available time points (baseline through 12 months) for each participant. For retreated individuals, outcomes recorded after retreatment were excluded from the models. This table presents the last available time point prior to retreatment that was included in the models for retreated participants.

eTable 5. Post-operative Complications.

Complication	*Combined Group*	*Sling Only Group*	*P-value*
Postoperative need for catheter and/or intermittent self catheterization at or beyond 2 weeks	4/242 (1.7)	5/238 (2.1)	0.72
Other wound healing problems >6 weeks	4/242 (1.7)	3/238 (1.3)	0.72
New/worsening vaginal infection	15/242 (6.2)	17/238 (7.1)	0.68
Urinary tract infection beyond 2 weeks	53/242 (21.9)	56/238 (23.5)	0.67
Other infection possibly related to intervention (sling or combined treatment)	2/242 (0.8)	5/238 (2.1)	0.24
Non-study health care provider visit due to complication related to intervention (sling or combined treatment)	1/242 (0.4)	2/238 (0.8)	0.55
Hospital readmission related to intervention (sling or combined treatment)	3/242 (1.2)	5/238 (2.1)	0.46
Any adverse events[a]	179/242 (74.0)	169/238 (71.0)	0.48
Any serious adverse events[a]	21/242 (8.7)	28/238 (11.8)	0.29
Any serious adverse event that is considered 'possibly, probably or definitely related' [b]	3 (1.2%)	8 (3.4%)	0.14
An adverse event that is considered 'unexpected' and 'possibly, probably or definitely related'[b]	32/242 (13.2)	36/238 (15.1)	0.55

[a] Includes any reported event, regardless of relatedness to incontinence treatment

[b] Relationship defined by investigators at clinical recruiting sites

eTable 6. All Adverse Events by System Organ Class and Preferred Term Reported.

		Combined Group (N=242)		*Sling Only Group (N=238)*	
System Organ Class	***Event***	***No. of Events***	***No. of Subjects (%)***	***No. of Events***	***No. of Subjects (%)***
Any	Any	657	179 (74%)	593	169 (71%)
Blood and lymphatic system disorders	Any	2	2 (1%)	3	3 (1%)
	Anemia	2	2 (1%)	3	3 (1%)
Cardiac disorders	Any	6	5 (2%)	7	7 (3%)
	Acute myocardial infarction	0	0 (0%)	1	1 (0%)
	Angina unstable	0	0 (0%)	1	1 (0%)
	Arrhythmia supraventricular	1	1 (0%)	0	0 (0%)
	Atrial fibrillation	0	0 (0%)	3	3 (1%)
	Atrial flutter	1	1 (0%)	0	0 (0%)
	Palpitations	3	3 (1%)	1	1 (0%)
	Pericardial effusion	1	1 (0%)	0	0 (0%)
	Sinus tachycardia	0	0 (0%)	1	1 (0%)
Congenital, familial and genetic disorders	Any	0	0 (0%)	1	1 (0%)
	Argininosuccinate lyase deficiency	0	0 (0%)	1	1 (0%)
Ear and labyrinth disorders	Any	3	3 (1%)	7	6 (3%)
	Ear pain	1	1 (0%)	3	3 (1%)
	Eustachian tube dysfunction	1	1 (0%)	0	0 (0%)
	Tinnitus	0	0 (0%)	2	2 (1%)
	Vertigo	0	0 (0%)	2	2 (1%)
	Vertigo positional	1	1 (0%)	0	0 (0%)
Endocrine disorders	Any	0	0 (0%)	1	1 (0%)
	Hypothyroidism	0	0 (0%)	1	1 (0%)
Eye disorders	Any	9	8 (3%)	6	5 (2%)
	Blepharitis	0	0 (0%)	2	2 (1%)
	Blepharochalasis	1	1 (0%)	0	0 (0%)
	Conjunctival hemorrhage	0	0 (0%)	1	1 (0%)
	Conjunctivitis allergic	1	1 (0%)	0	0 (0%)
	Dry eye	1	1 (0%)	2	2 (1%)
	Eyelid ptosis	1	1 (0%)	0	0 (0%)
	Glaucoma	1	1 (0%)	0	0 (0%)
	Periorbital edema	1	1 (0%)	0	0 (0%)
	Pinguecula	1	1 (0%)	0	0 (0%)
	Pterygium	1	1 (0%)	0	0 (0%)
	Retinal detachment	1	1 (0%)	0	0 (0%)
	Vision blurred	0	0 (0%)	1	1 (0%)
Gastrointestinal disorders	Any	71	46 (19%)	72	50 (21%)
	Abdominal distension	0	0 (0%)	2	2 (1%)
	Abdominal pain	13	11 (5%)	13	11 (5%)
	Abdominal pain lower	4	4 (2%)	5	5 (2%)
	Abdominal pain upper	2	2 (1%)	3	3 (1%)
	Cheilitis	1	1 (0%)	0	0 (0%)
	Colitis microscopic	0	0 (0%)	1	1 (0%)
	Constipation	16	14 (6%)	9	9 (4%)
	Diarrhea	7	7 (3%)	6	6 (3%)
	Diverticulum intestinal	1	1 (0%)	0	0 (0%)
	Dyspepsia	4	4 (2%)	1	1 (0%)
	Fecal incontinence	2	2 (1%)	1	1 (0%)

		Combined Group (N=242)		*Sling Only Group (N=238)*	
System Organ Class	***Event***	***No. of Events***	***No. of Subjects (%)***	***No. of Events***	***No. of Subjects (%)***
	Functional gastrointestinal disorder	0	0 (0%)	1	1 (0%)
	Gastritis	1	1 (0%)	2	2 (1%)
	Gastroesophageal reflux disease	1	1 (0%)	2	2 (1%)
	Gingival swelling	0	0 (0%)	1	1 (0%)
	Hemorrhoids	1	1 (0%)	4	4 (2%)
	Irritable bowel syndrome	1	1 (0%)	2	2 (1%)
	Large intestinal obstruction	0	0 (0%)	1	1 (0%)
	Levator syndrome	3	3 (1%)	2	2 (1%)
	Nausea	5	4 (2%)	8	8 (3%)
	Pancreatitis acute	0	0 (0%)	3	3 (1%)
	Proctalgia	1	1 (0%)	0	0 (0%)
	Rectal hemorrhage	1	1 (0%)	0	0 (0%)
	Retroperitoneal hematoma	1	1 (0%)	0	0 (0%)
	Stomatitis	1	1 (0%)	0	0 (0%)
	Toothache	1	1 (0%)	0	0 (0%)
	Umbilical hernia	1	1 (0%)	0	0 (0%)
	Vomiting	3	3 (1%)	5	4 (2%)
General disorders and administration site conditions	Any	27	25 (10%)	22	21 (9%)
	Adverse drug reaction	1	1 (0%)	0	0 (0%)
	Asthenia	0	0 (0%)	1	1 (0%)
	Catheter site pain	1	1 (0%)	0	0 (0%)
	Chest discomfort	0	0 (0%)	2	2 (1%)
	Chest pain	5	5 (2%)	6	6 (3%)
	Chills	0	0 (0%)	1	1 (0%)
	Discomfort	1	1 (0%)	0	0 (0%)
	Facial pain	1	1 (0%)	0	0 (0%)
	Fatigue	2	2 (1%)	0	0 (0%)
	Hernia pain	0	0 (0%)	1	1 (0%)
	Inflammation	0	0 (0%)	1	1 (0%)
	Local swelling	0	0 (0%)	2	2 (1%)
	Malaise	0	0 (0%)	1	1 (0%)
	Medical device site reaction	4	4 (2%)	2	2 (1%)
	Non-cardiac chest pain	0	0 (0%)	1	1 (0%)
	Edema peripheral	2	2 (1%)	3	3 (1%)
	Pain	2	2 (1%)	0	0 (0%)
	Polyp	1	1 (0%)	0	0 (0%)
	Pyrexia	1	1 (0%)	1	1 (0%)
	Suprapubic pain	6	6 (2%)	0	0 (0%)
Hepatobiliary disorders	Any	4	3 (1%)	2	2 (1%)
	Bile duct stone	0	0 (0%)	1	1 (0%)
	Biliary colic	1	1 (0%)	0	0 (0%)
	Cholecystitis	1	1 (0%)	0	0 (0%)
	Cholelithiasis	2	2 (1%)	0	0 (0%)
	Hyperplastic cholecystopathy	0	0 (0%)	1	1 (0%)
Immune system disorders	Any	5	5 (2%)	3	3 (1%)
	Allergic edema	0	0 (0%)	1	1 (0%)
	Drug hypersensitivity	1	1 (0%)	0	0 (0%)
	Food allergy	0	0 (0%)	1	1 (0%)
	Hypersensitivity	4	4 (2%)	0	0 (0%)

		Combined Group (N=242)		***Sling Only Group (N=238)***	
System Organ Class	***Event***	***No. of Events***	***No. of Subjects (%)***	***No. of Events***	***No. of Subjects (%)***
	Seasonal allergy	0	0 (0%)	1	1 (0%)
Infections and infestations	Any	162	88 (36%)	160	101 (42%)
	Abscess limb	1	1 (0%)	0	0 (0%)
	Acute sinusitis	3	3 (1%)	1	1 (0%)
	Appendicitis	0	0 (0%)	1	1 (0%)
	Atypical pneumonia	2	2 (1%)	0	0 (0%)
	Bacterial vaginosis	4	4 (2%)	0	0 (0%)
	Balanitis candida	1	1 (0%)	0	0 (0%)
	Body tinea	0	0 (0%)	2	2 (1%)
	Bronchitis	3	3 (1%)	4	4 (2%)
	Bronchitis bacterial	1	1 (0%)	0	0 (0%)
	Bronchitis viral	0	0 (0%)	1	1 (0%)
	Candida infection	0	0 (0%)	2	2 (1%)
	Cellulitis	4	4 (2%)	1	1 (0%)
	Cervicitis	1	1 (0%)	0	0 (0%)
	Chronic sinusitis	1	1 (0%)	0	0 (0%)
	Clostridium difficile colitis	1	1 (0%)	0	0 (0%)
	Conjunctivitis	1	1 (0%)	4	4 (2%)
	Diarrhea infectious	1	1 (0%)	0	0 (0%)
	Diverticulitis	0	0 (0%)	1	1 (0%)
	Ear infection	0	0 (0%)	2	2 (1%)
	Eye infection	1	1 (0%)	0	0 (0%)
	Folliculitis	0	0 (0%)	1	1 (0%)
	Fungal infection	2	1 (0%)	9	8 (3%)
	Furuncle	2	2 (1%)	2	2 (1%)
	Gastroenteritis	4	4 (2%)	4	3 (1%)
	Gastroenteritis viral	0	0 (0%)	1	1 (0%)
	Helicobacter infection	2	2 (1%)	0	0 (0%)
	Herpes simplex	1	1 (0%)	0	0 (0%)
	Herpes zoster	2	2 (1%)	0	0 (0%)
	Impetigo	0	0 (0%)	1	1 (0%)
	Incision site infection	1	1 (0%)	1	1 (0%)
	Infected bunion	1	1 (0%)	0	0 (0%)
	Influenza	4	4 (2%)	3	3 (1%)
	Nail bed infection fungal	1	1 (0%)	0	0 (0%)
	Nasopharyngitis	1	1 (0%)	3	2 (1%)
	Onychomycosis	3	3 (1%)	0	0 (0%)
	Otitis externa	0	0 (0%)	3	2 (1%)
	Otitis media	1	1 (0%)	1	1 (0%)
	Pharyngitis streptococcal	1	1 (0%)	0	0 (0%)
	Pneumonia	1	1 (0%)	3	3 (1%)
	Pyelonephritis	1	1 (0%)	2	2 (1%)
	Pyelonephritis acute	1	1 (0%)	0	0 (0%)
	Rhinitis	1	1 (0%)	0	0 (0%)
	Sinusitis	8	8 (3%)	9	8 (3%)
	Sinusitis bacterial	0	0 (0%)	1	1 (0%)
	Skin candida	0	0 (0%)	1	1 (0%)
	Skin infection	1	1 (0%)	0	0 (0%)
	Tooth infection	1	1 (0%)	0	0 (0%)
	Upper respiratory tract infection	7	7 (3%)	12	11 (5%)
	Urinary tract infection	74	58 (24%)	76	61 (26%)

		Combined Group (N=242)		*Sling Only Group (N=238)*	
System Organ Class	***Event***	***No. of Events***	***No. of Subjects (%)***	***No. of Events***	***No. of Subjects (%)***
	Vaginal infection	5	5 (2%)	1	1 (0%)
	Vaginitis bacterial	0	0 (0%)	1	1 (0%)
	Vestibular neuronitis	1	1 (0%)	0	0 (0%)
	Viral infection	1	1 (0%)	0	0 (0%)
	Viral upper respiratory tract infection	1	1 (0%)	1	1 (0%)
	Vulvitis	1	1 (0%)	0	0 (0%)
	Vulvovaginal candidiasis	3	2 (1%)	2	2 (1%)
	Vulvovaginal mycotic infection	3	3 (1%)	2	2 (1%)
	Wound infection	1	1 (0%)	1	1 (0%)
Injury, poisoning and procedural complications	Any	32	24 (10%)	21	19 (8%)
	Animal bite	0	0 (0%)	2	2 (1%)
	Ankle fracture	1	1 (0%)	0	0 (0%)
	Back injury	0	0 (0%)	1	1 (0%)
	Bladder injury	0	0 (0%)	1	1 (0%)
	Contusion	2	2 (1%)	1	1 (0%)
	Epicondylitis	1	1 (0%)	0	0 (0%)
	Exposure to allergen	1	1 (0%)	0	0 (0%)
	Facial bones fracture	1	1 (0%)	0	0 (0%)
	Fall	3	3 (1%)	4	4 (2%)
	Foot fracture	0	0 (0%)	2	2 (1%)
	Foreign body	1	1 (0%)	0	0 (0%)
	Hand fracture	1	1 (0%)	0	0 (0%)
	Humerus fracture	0	0 (0%)	1	1 (0%)
	Iliotibial band syndrome	1	1 (0%)	0	0 (0%)
	Incision site complication	0	0 (0%)	1	1 (0%)
	Incision site hemorrhage	1	1 (0%)	0	0 (0%)
	Incision site pain	2	2 (1%)	0	0 (0%)
	Joint injury	0	0 (0%)	1	1 (0%)
	Laceration	0	0 (0%)	1	1 (0%)
	Ligament sprain	2	2 (1%)	1	1 (0%)
	Limb injury	1	1 (0%)	1	1 (0%)
	Muscle strain	3	3 (1%)	1	1 (0%)
	Post procedural hemorrhage	0	0 (0%)	1	1 (0%)
	Procedural nausea	1	1 (0%)	0	0 (0%)
	Procedural pain	4	4 (2%)	1	1 (0%)
	Procedural vomiting	1	1 (0%)	0	0 (0%)
	Road traffic accident	1	1 (0%)	0	0 (0%)
	Suture related complication	1	1 (0%)	0	0 (0%)
	Thermal burn	0	0 (0%)	1	1 (0%)
	Vulvovaginal injury	1	1 (0%)	0	0 (0%)
	Wound dehiscence	1	1 (0%)	0	0 (0%)
	Wrist fracture	1	1 (0%)	0	0 (0%)
Investigations	Any	9	7 (3%)	8	6 (3%)
	Anti-thyroid antibody	0	0 (0%)	1	1 (0%)
	Blood cholesterol increased	1	1 (0%)	2	2 (1%)
	Blood pressure increased	2	2 (1%)	1	1 (0%)
	Blood thyroid stimulating hormone increase	0	0 (0%)	1	1 (0%)
	C-reactive protein increased	1	1 (0%)	0	0 (0%)
	Cardiovascular function test abnormal	1	1 (0%)	0	0 (0%)

		Combined Group (N=242)		*Sling Only Group (N=238)*	
System Organ Class	***Event***	***No. of Events***	***No. of Subjects (%)***	***No. of Events***	***No. of Subjects (%)***
	Erythrocytes sedimentation rate increased	1	1 (0%)	0	0 (0%)
	Glycosylated hemoglobin increased	0	0 (0%)	2	2 (1%)
	Helicobacter test positive	2	2 (1%)	0	0 (0%)
	Prealbumin abnormal	1	1 (0%)	0	0 (0%)
	Vitamin D decreased	0	0 (0%)	1	1 (0%)
Metabolism and nutrition disorders	Any	4	4 (2%)	4	3 (1%)
	Dehydration	1	1 (0%)	0	0 (0%)
	Diabetes mellitus inadequate control	0	0 (0%)	1	1 (0%)
	Electrolyte imbalance	0	0 (0%)	1	1 (0%)
	Glucose tolerance impaired	1	1 (0%)	1	1 (0%)
	Hypercholesterolemia	1	1 (0%)	0	0 (0%)
	Hypokalemia	1	1 (0%)	0	0 (0%)
	Vitamin D deficiency	0	0 (0%)	1	1 (0%)
Musculoskeletal and connective tissue disorders	Any	103	61 (25%)	66	49 (21%)
	Arthralgia	24	18 (7%)	8	6 (3%)
	Arthritis	1	1 (0%)	1	1 (0%)
	Back pain	20	18 (7%)	12	12 (5%)
	Bursitis	1	1 (0%)	1	1 (0%)
	Costochondritis	1	1 (0%)	1	1 (0%)
	Diastasis recti abdominis	1	1 (0%)	0	0 (0%)
	Fibromyalgia	5	5 (2%)	1	1 (0%)
	Flank pain	1	1 (0%)	1	1 (0%)
	Groin pain	2	2 (1%)	1	1 (0%)
	Intervertebral disc annular tear	0	0 (0%)	1	1 (0%)
	Intervertebral disc degeneration	1	1 (0%)	1	1 (0%)
	Intervertebral disc protrusion	1	1 (0%)	0	0 (0%)
	Joint range of motion decreased	1	1 (0%)	0	0 (0%)
	Joint swelling	1	1 (0%)	3	2 (1%)
	Muscle spasms	5	4 (2%)	1	1 (0%)
	Muscle tightness	0	0 (0%)	1	1 (0%)
	Muscular weakness	1	1 (0%)	0	0 (0%)
	Musculoskeletal discomfort	1	1 (0%)	0	0 (0%)
	Musculoskeletal pain	1	1 (0%)	4	4 (2%)
	Myalgia	1	1 (0%)	0	0 (0%)
	Myofascial pain syndrome	0	0 (0%)	1	1 (0%)
	Neck pain	5	4 (2%)	2	2 (1%)
	Osteoarthritis	7	6 (2%)	8	7 (3%)
	Osteoporosis	1	1 (0%)	0	0 (0%)
	Pain in extremity	9	8 (3%)	11	11 (5%)
	Plantar fasciitis	4	4 (2%)	1	1 (0%)
	Pubic pain	1	1 (0%)	0	0 (0%)
	Rheumatoid arthritis	0	0 (0%)	2	2 (1%)
	Rotator cuff syndrome	4	4 (2%)	0	0 (0%)
	Spinal osteoarthritis	1	1 (0%)	0	0 (0%)
	Synovial cyst	1	1 (0%)	2	2 (1%)
	Systemic lupus erythematosus	0	0 (0%)	1	1 (0%)

		Combined Group (N=242)		*Sling Only Group (N=238)*	
System Organ Class	***Event***	***No. of Events***	***No. of Subjects (%)***	***No. of Events***	***No. of Subjects (%)***
	Tendonitis	1	1 (0%)	1	1 (0%)
Neoplasms benign, malignant and unspecified	Any	9	9 (4%)	7	6 (3%)
	B-cell lymphoma	1	1 (0%)	0	0 (0%)
	Benign breast neoplasm	1	1 (0%)	0	0 (0%)
	Breast cancer	1	1 (0%)	0	0 (0%)
	Colon adenoma	1	1 (0%)	0	0 (0%)
	Colon cancer stage IV	0	0 (0%)	1	1 (0%)
	Lip squamous cell carcinoma	1	1 (0%)	0	0 (0%)
	Malignant melanoma	0	0 (0%)	1	1 (0%)
	Melanocytic nevus	1	1 (0%)	1	1 (0%)
	Ovarian fibroma	0	0 (0%)	1	1 (0%)
	Seborrheic keratosis	1	1 (0%)	1	1 (0%)
	Uterine leiomyoma	2	2 (1%)	2	2 (1%)
Nervous system disorders	Any	40	30 (12%)	36	30 (13%)
	Amnesia	1	1 (0%)	1	1 (0%)
	Balance disorder	0	0 (0%)	1	1 (0%)
	Burning sensation	1	1 (0%)	0	0 (0%)
	Carpal tunnel syndrome	1	1 (0%)	2	2 (1%)
	Central nervous system lesion	1	1 (0%)	0	0 (0%)
	Cerebral small vessel ischemic disease	0	0 (0%)	1	1 (0%)
	Cerebrovascular accident	0	0 (0%)	1	1 (0%)
	Cervical radiculopathy	1	1 (0%)	0	0 (0%)
	Dizziness	3	3 (1%)	4	4 (2%)
	Femoral nerve palsy	0	0 (0%)	1	1 (0%)
	Headache	10	9 (4%)	6	6 (3%)
	Hypertensive encephalopathy	0	0 (0%)	1	1 (0%)
	Hypoesthesia	1	1 (0%)	4	3 (1%)
	Loss of consciousness	1	1 (0%)	0	0 (0%)
	Lumbar radiculopathy	0	0 (0%)	1	1 (0%)
	Meralgia paraesthetica	1	1 (0%)	0	0 (0%)
	Migraine	4	3 (1%)	4	4 (2%)
	Morton's neuralgia	1	1 (0%)	0	0 (0%)
	Multiple sclerosis	0	0 (0%)	1	1 (0%)
	Neuralgia	0	0 (0%)	1	1 (0%)
	Paraesthesia	0	0 (0%)	1	1 (0%)
	Piriformis syndrome	1	1 (0%)	0	0 (0%)
	Radicular pain	1	1 (0%)	0	0 (0%)
	Radiculitis	0	0 (0%)	1	1 (0%)
	Radiculopathy	1	1 (0%)	1	1 (0%)
	Resting tremor	1	1 (0%)	0	0 (0%)
	Sciatica	6	6 (2%)	1	1 (0%)
	Sinus headache	1	1 (0%)	0	0 (0%)
	Somnolence	1	1 (0%)	0	0 (0%)
	Spondylitic myelopathy	0	0 (0%)	1	1 (0%)
	Syncope	1	1 (0%)	1	1 (0%)
	Tension headache	0	0 (0%)	1	1 (0%)
	Visual field defect	1	1 (0%)	0	0 (0%)
Psychiatric disorders	Any	7	7 (3%)	13	11 (5%)
	Anxiety	1	1 (0%)	6	6 (3%)
	Anxiety disorder	1	1 (0%)	0	0 (0%)

		Combined Group (N=242)		*Sling Only Group (N=238)*	
System Organ Class	***Event***	***No. of Events***	***No. of Subjects (%)***	***No. of Events***	***No. of Subjects (%)***
	Bipolar I disorder	1	1 (0%)	0	0 (0%)
	Depression	0	0 (0%)	5	5 (2%)
	Grief reaction	0	0 (0%)	1	1 (0%)
	Insomnia	2	2 (1%)	0	0 (0%)
	Libido decreased	0	0 (0%)	1	1 (0%)
	Mental status changes	1	1 (0%)	0	0 (0%)
	Panic attack	1	1 (0%)	0	0 (0%)
Renal and urinary disorders	Any	33	30 (12%)	40	34 (14%)
	Bladder pain	0	0 (0%)	2	2 (1%)
	Bladder perforation	1	1 (0%)	1	1 (0%)
	Chronic kidney disease	0	0 (0%)	1	1 (0%)
	Cystitis hemorrhagic	1	1 (0%)	0	0 (0%)
	Dysuria	7	7 (3%)	3	3 (1%)
	Hematuria	2	2 (1%)	1	1 (0%)
	Micturition urgency	2	2 (1%)	3	3 (1%)
	Nephrolithiasis	0	0 (0%)	5	5 (2%)
	Pollakiuria	1	1 (0%)	2	1 (0%)
	Prerenal failure	0	0 (0%)	1	1 (0%)
	Proteinuria	0	0 (0%)	1	1 (0%)
	Stress urinary incontinence	1	1 (0%)	0	0 (0%)
	Urethral discharge	0	0 (0%)	1	1 (0%)
	Urge incontinence	0	0 (0%)	2	2 (1%)
	Urinary retention	18	17 (7%)	17	17 (7%)
Reproductive system and breast disorders	Any	61	42 (17%)	59	46 (19%)
	Adnexa uteri mass	1	1 (0%)	0	0 (0%)
	Atrophic vulvovaginitis	3	3 (1%)	2	2 (1%)
	Bartholin's cyst	0	0 (0%)	2	2 (1%)
	Breast discharge	1	1 (0%)	0	0 (0%)
	Breast mass	2	2 (1%)	0	0 (0%)
	Breast pain	0	0 (0%)	1	1 (0%)
	Dyspareunia	11	11 (5%)	13	13 (5%)
	Genital pain	4	4 (2%)	15	15 (6%)
	Labia enlarged	1	1 (0%)	0	0 (0%)
	Menometrorrhagia	0	0 (0%)	1	1 (0%)
	Menorrhagia	1	1 (0%)	0	0 (0%)
	Metrorrhagia	0	0 (0%)	1	1 (0%)
	Ovarian cyst	3	3 (1%)	0	0 (0%)
	Ovarian cyst ruptured	1	1 (0%)	0	0 (0%)
	Ovulation pain	0	0 (0%)	1	1 (0%)
	Pelvic floor muscle weakness	0	0 (0%)	1	1 (0%)
	Pelvic hematoma	1	1 (0%)	0	0 (0%)
	Pelvic pain	7	6 (2%)	4	4 (2%)
	Perineal pain	1	1 (0%)	1	1 (0%)
	Postmenopausal hemorrhage	1	1 (0%)	0	0 (0%)
	Pruritus genital	0	0 (0%)	1	1 (0%)
	Vaginal cyst	1	1 (0%)	0	0 (0%)
	Vaginal discharge	2	2 (1%)	1	1 (0%)
	Vaginal enlargement	0	0 (0%)	1	1 (0%)
	Vaginal hemorrhage	8	8 (3%)	6	6 (3%)
	Vaginal prolapse	1	1 (0%)	0	0 (0%)
	Vulva cyst	1	1 (0%)	0	0 (0%)

		Combined Group (N=242)		*Sling Only Group (N=238)*	
System Organ Class	***Event***	***No. of Events***	***No. of Subjects (%)***	***No. of Events***	***No. of Subjects (%)***
	Vulvovaginal burning sensation	1	1 (0%)	0	0 (0%)
	Vulvovaginal discomfort	1	1 (0%)	2	2 (1%)
	Vulvovaginal erythema	0	0 (0%)	1	1 (0%)
	Vulvovaginal pain	5	5 (2%)	1	1 (0%)
	Vulvovaginal pruritus	3	3 (1%)	4	4 (2%)
Respiratory, thoracic and mediastinal disorders	Any	33	24 (10%)	26	22 (9%)
	Asthma	9	7 (3%)	6	5 (2%)
	Bronchial hyperreactivity	0	0 (0%)	1	1 (0%)
	Bronchospasm	1	1 (0%)	0	0 (0%)
	Choking	0	0 (0%)	1	1 (0%)
	Chronic obstructive pulmonary disease	1	1 (0%)	1	1 (0%)
	Cough	10	9 (4%)	7	7 (3%)
	Dyspnea	2	2 (1%)	2	2 (1%)
	Hypoxia	1	1 (0%)	1	1 (0%)
	Nasal congestion	1	1 (0%)	0	0 (0%)
	Oropharyngeal pain	1	1 (0%)	2	2 (1%)
	Pleurisy	1	1 (0%)	0	0 (0%)
	Pulmonary embolism	1	1 (0%)	0	0 (0%)
	Pulmonary mass	0	0 (0%)	1	1 (0%)
	Pulmonary sarcoidosis	1	1 (0%)	0	0 (0%)
	Rhinitis allergic	1	1 (0%)	2	2 (1%)
	Sleep apnea syndrome	0	0 (0%)	1	1 (0%)
	Tonsillar hypertrophy	0	0 (0%)	1	1 (0%)
	Tonsillolith	1	1 (0%)	0	0 (0%)
	Upper respiratory tract congestion	1	1 (0%)	0	0 (0%)
	Wheezing	1	1 (0%)	0	0 (0%)
Skin and subcutaneous tissue disorders	Any	19	17 (7%)	12	9 (4%)
	Actinic keratosis	3	3 (1%)	1	1 (0%)
	Alopecia	1	1 (0%)	0	0 (0%)
	Dermatitis	3	3 (1%)	1	1 (0%)
	Dermatitis allergic	1	1 (0%)	0	0 (0%)
	Ecchymosis	2	2 (1%)	0	0 (0%)
	Excessive granulation tissue	0	0 (0%)	1	1 (0%)
	Hand dermatitis	0	0 (0%)	1	1 (0%)
	Hyperhidrosis	0	0 (0%)	1	1 (0%)
	Hyperkeratosis	1	1 (0%)	0	0 (0%)
	Ingrown nail	0	0 (0%)	1	1 (0%)
	Intertrigo	1	1 (0%)	0	0 (0%)
	Night sweats	1	1 (0%)	0	0 (0%)
	Pruritus	2	2 (1%)	2	2 (1%)
	Psoriasis	1	1 (0%)	0	0 (0%)
	Rash	1	1 (0%)	1	1 (0%)
	Skin lesion	1	1 (0%)	1	1 (0%)
	Urticaria	1	1 (0%)	2	2 (1%)
Surgical and medical procedures	Any	14	14 (6%)	10	10 (4%)
	Bartholin's cyst removal	0	0 (0%)	1	1 (0%)
	Bladder neck suspension	0	0 (0%)	2	2 (1%)

		Combined Group (N=242)		*Sling Only Group (N=238)*	
System Organ Class	***Event***	***No. of Events***	***No. of Subjects (%)***	***No. of Events***	***No. of Subjects (%)***
	Bladder operation	1	1 (0%)	0	0 (0%)
	Cataract operation	1	1 (0%)	0	0 (0%)
	Endodontic procedure	1	1 (0%)	1	1 (0%)
	Foot operation	0	0 (0%)	1	1 (0%)
	Gastrectomy	1	1 (0%)	0	0 (0%)
	Gastric bypass	1	1 (0%)	1	1 (0%)
	High frequency ablation	1	1 (0%)	0	0 (0%)
	Incisional drainage	1	1 (0%)	0	0 (0%)
	Inguinal hernia repair	1	1 (0%)	0	0 (0%)
	Knee arthroplasty	1	1 (0%)	0	0 (0%)
	Knee operation	1	1 (0%)	0	0 (0%)
	Mastectomy	1	1 (0%)	0	0 (0%)
	Medical device implantation	0	0 (0%)	1	1 (0%)
	Tendon operation	0	0 (0%)	1	1 (0%)
	Tooth extraction	1	1 (0%)	1	1 (0%)
	Tympanoplasty	1	1 (0%)	0	0 (0%)
	Umbilical hernia repair	0	0 (0%)	1	1 (0%)
	Vaginectomy	1	1 (0%)	0	0 (0%)
Vascular disorders	Any	4	4 (2%)	7	7 (3%)
	Hematoma	2	2 (1%)	1	1 (0%)
	Hemorrhage	0	0 (0%)	1	1 (0%)
	Hot flush	0	0 (0%)	2	2 (1%)
	Hypertension	1	1 (0%)	3	3 (1%)
	Varicose vein	1	1 (0%)	0	0 (0%)