Supplementary Appendix

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

Supplement to: Richter HE, Albo ME, Zyczynski HM, et al. Retropubic versus transobturator midurethral slings for stress incontinence. N Engl J Med 2010;362:2066-76. DOI: 10.1056/NEJMoa0912658.

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Web Table 1. Other Demographic, Anthropometric, Clinical, Urodynamic and Surgical Characteristics of the Study Population*

Characteristic	Retropubic (n=298)	Transobturator (n=299)
Demographic Characteristics		
Marital Status		
Married/Living as Married	203 (68)	209 (70)
Not Married	95 (32)	90 (30)
Education		
High School or less	89 (30)	95 (32)
Some post-high school training	116 (39)	101 (34)
Baccalaureate or more	93 (31)	103 (34)
Smoking Status		
Never smoked	158 (53)	161 (54)
Former smoker	96 (32)	102 (34)
Current smoker	44 (15)	36 (12)
Menopause and hormone replacement		
Postmenopausal and current hormone replacement therapy	81 (27)	90 (30)
Postmenopausal and no current hormone replacement therapy	128 (43)	116 (39)
Pre-menopausal	88 (30)	92 (31)
Pelvic Organ Prolapse Quantification Stage †		

Stage 0/I	130 (44)	137 (46)
Stage II	144 (48)	138 (46)
Stage III/IV	24 (8)	24 (8)
Urodynamic Measures‡		
Leakage when determining Valsalva leak point pressure (VLPP)		
Leak with Valsalva	206 (71)	212 (71)
Leak with cough at MCC	40 (14)	47 (16)
Did not leak	45 (15)	39 (13)
Surgical Characteristics		
Surgeries		
Concomitant Surgery §	73 (25)	78 (26)
Vault Suspension	21 (7)	18 (6)
Anterior vaginal wall repair	25 (8)	28 (9)
Posterior repair/perineorrhaphy	35 (12)	36 (12)
Vaginal hysterectomy +/- bilateral salpingo-oophorectomy	25 (8)	21 (7)
Bilateral salpingo-oophorectomy	8 (3)	6 (2)
Anal sphincteroplasty	1 (0.3)	2 (0.7)
Colpocleisis	2 (1)	6 (2)

Enterocele repair	3 (1)	4 (1)
Other concomitant surgery	12 (4)	15 (5)

* Plus-minus values are means ± SD unless otherwise indicated. Percentages may not total 100 because of rounding. Stand alone values with parentheses are n (%).

†Prolapse staging is based on the methods of the Pelvic Organ Prolapse Quantification system.[1]

‡Valsalva leak point pressure (VLPP) refers to the vesical pressure at the time of leakage.

§Concomitant surgery includes vault suspension (uterosacral ligament vault suspension, sacrospinous ligament suspension, iliococcygeus vault suspension), anterior vaginal wall repair (anterior colporrhaphy, vaginal paravaginal repair), posterior repair/perineorrhaphy (standard posterior colporrhaphy, defect-directed posterior repair, posterior repair with allograft or autograft), vaginal hysterectomy with or without bilateral salpingo oophorectomy, bilateral salpingo oophorectomy, anal sphincteroplasty, colpocleisis, enterocele repair and other. A person could have more than one concomitant surgery, so categories do not sum to the total who had concomitant surgery.

Reference:

1. Bump RC, Mattiasson A, Bø K, et al. The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. Am J Obstet Gynecol 1996:175:10-7.

Web Table 2.* Adverse Events[a] by Treatment Group, Severity[b], and System

	Treatment	
	Retropubic (N=298)	**Transobturator (N=299)**
System Events	Number of events	Number of events
Adverse Events (AE), (Grades I-II)		
Genitourinary	46	27
Cystitis – culture proven	23	15
Cystitis – empirically treated	15	8
Recurrent cystitis[c]	8	4
Vascular/hematologic	20	7
Intraoperative bleeding[d]	14	7
Postoperative bleeding	6	0
Neurologic symptoms[e]	15	31
Numbness	8	9
Suprapubic	2	1
Groin	1	2
Vulva	2	0

	Treatment	
	Retropubic (N=298)	**Transobturator (N=299)**
Upper leg	0	5
Lower leg	3	1
Weakness	7	22
Upper leg	4	20
Lower leg	3	2
Voiding dysfunction	16	5
Managed with catheter at ≥6 weeks postoperatively (not medicine, behavioral or neuromodulation)	11	2
Managed with medical therapy at ≥6 weeks postoperatively	2	1
Managed with behavioral or neuromodulation (with or without catheter use)	3	2
Pain[f] per patient self-report ≥6	7	7

	Treatment	
	Retropubic (N=298)	**Transobturator (N=299)**
weeks		
Suprapubic and Groin	3	2
Suprapubic only	3	3
Other	1	2
Other[g]	7	6

* This is not a complete list of adverse events; this expands on adverse events presented in the main text.

Note: One subject randomized to the retropubic procedure received a transobturator sling and had a culture proven cystitis; one subject randomized to the transobturator procedure received the retropubic procedure and had no SAE's or AE's.

[a] Adverse event (AE) defined as a deviation from the normal intra- or post-operative course (Grades I and II). A single patient can have multiple entries.

[b] Severity grade determined by a slightly modified version of the Dindo[1] classification system, which is based on the level of therapy required to treat an event. Serious Adverse Event (SAE) defined as ≥ Grade III-V; no grade IV or V events occurred in either group.

I – No pharmacologic, surgical, or radiologic intervention (allowed therapeutic regimens include antiemetics, antipyretics, analgesics, diuretics, electrolytes, and physiotherapy).

II – Required pharmacologic treatment with drugs other than such allowed for grade I complications (antibiotics, blood transfusions and total parenteral nutrition are included).

III – Required surgical, endoscopic or radiologic intervention.

IV – Life-threatening complication requiring intensive care management.

V – Death.

[c] Recurrent cystitis defined as presumed UTI with treatment, ≥3 in 1 year after 6 week visit.

[d] Estimated blood loss (EBL) >100 cc due to sling placement or EBL for total case ≥1000 cc.

[e] Neurologic symptoms are defined by self report on standardized form of new paresthesias or alteration in motor function that developed between surgery and the 6 week visit. Symptoms were not assessed after the 6 week visit. The location of numbness or weakness was ascertained by the patient marking a body map. The one neurologic SAE was numbness occurring in the patient's upper leg. Neurologic AEs were listed by location.

[f] Pain defined as self report at or beyond 6 weeks post surgery by the following questions:

1. Patient answers "yes" to the introductory question "Have you had any pain within the last 24 hours as a result of your incontinence operation?" and
2. Patient answers any of the first three McCarthy[2] pain questions at a level 75mm or greater on the visual analog scale (150mm total length). and

3. Patient answers the bother question on the McCarthy visual analog scale at a level 75mm or greater.

[g] Other adverse events include: granulation tissue, anxiety, thrush, wound edge separation, minor wound, medication reaction and skin irritation.

References:

1. Dindo D, Demartines N, Clavien PA. Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. Ann Surg 2004;240:205-13.

2. McCarthy M Jr, Jonasson O, Chang CH, et al. Assessment of patient functional status after surgery. J Am Coll Surg 2005;201:171-8. [Erratum, J Am Coll Surg 2005:201;825.]

Web Table 3. Quality of Life Outcomes

	Treatment		
	Retropubic (N=298)	**Transobturator (N=299)**	**P Value[a]**
‡Change UDI total	106.8(48.0)	110.5(51.2)	0.40
‡Change UDI stress	61.6 (27.2)	61.8(27.7)	0.95
‡Change UDI irritative	30.2 (24.7)	33.6 (25.6)	0.12
‡Change UDI Obstructive	15.0 (17.9)	15.1(16.2)	0.95
‡Change IIQ total	111.6 (93.2)	118.7 (96.6)	0.40

[a] P-values are from least squares models predicting change in scores from treatment group.

‡ Mean (SD) of scores on the Urogenital Distress Inventory range from 0 to 300, with higher scores indicating greater distress. Scores on the Incontinence Impact Questionnaire range from 0 to 400, with higher scores indicating greater impact.[1] The scores are changes from baseline to the 12 month visit (baseline – 12 months).

Reference:

1. Shumaker SA, Wyman JF, Uebersax JS, McClish D, Fantl JA. Health-related quality of life measures for women with urinary incontinence: the Incontinence Impact Questionnaire and the Urogenital Distress Inventory. Qual Life Res 1994;3:291-306.

Web Figure 1. Retropubic (green) and Transobturator (blue) Midurethral Slings

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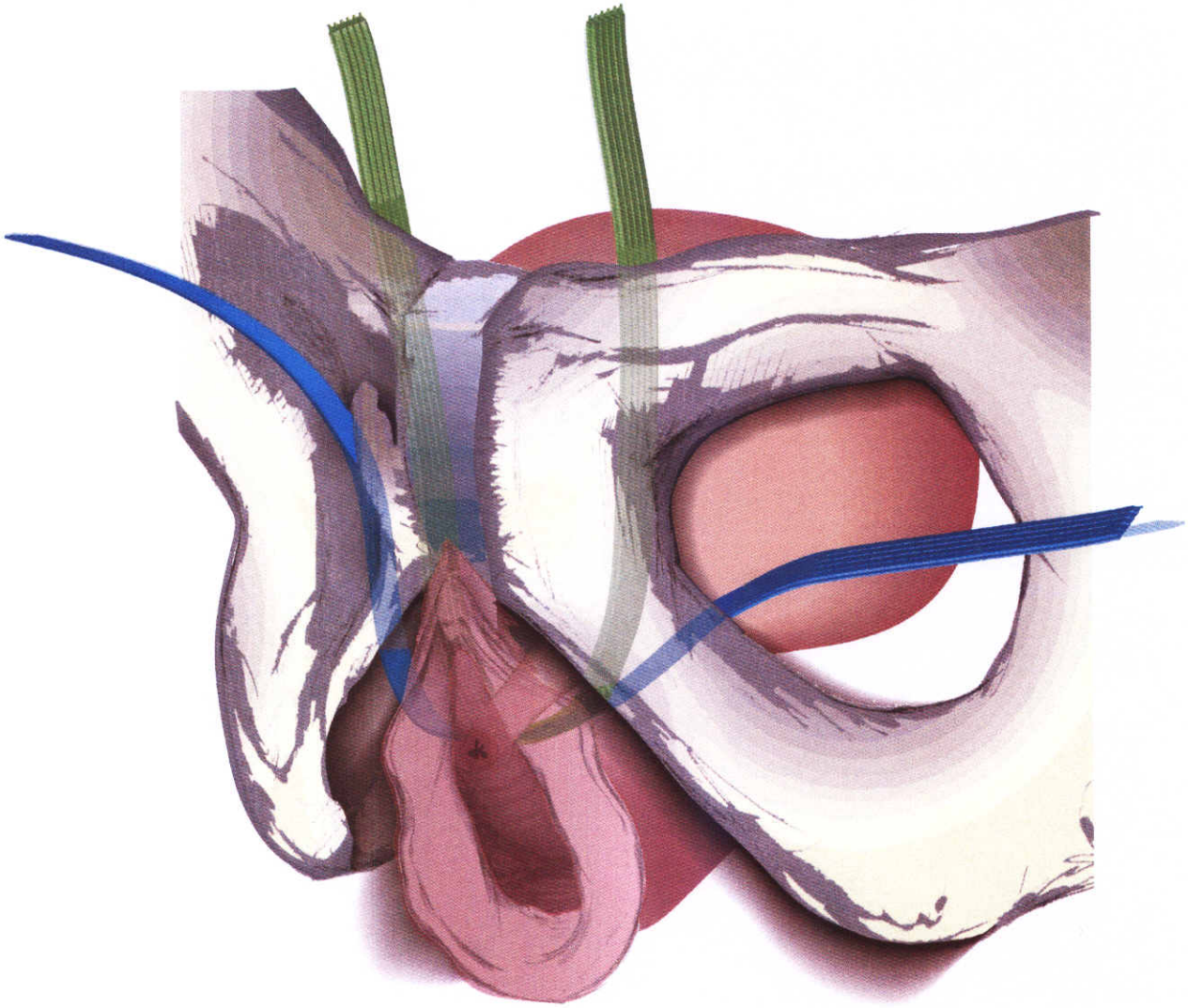

Figure 1.