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Presentation Title: FEMALE SEXUAL FUNCTION FOLLOWING SLING SURGERY: A PROSPECTIVE PARALLEL COHORT, MULTI-CENTER STUDY OF THE SOLYX™ SINGLE INCISION SLING SYSTEM VS. THE OBTRYX™ II SLING SYSTEM (FDA- MANDATED 522 RESULTS AT 36 MONTHS)

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Objective

Compare sexual function at 36 months postoperatively between patients undergoing single incision sling (SIS) and transobturator mid-urethral sling (TMUS) for treatment of stress urinary incontinence (SUI).

Methods

Assessment of sexual function was a planned secondary objective of a prospective study comparing SIS to TMUS. Primary study aim was to compare efficacy and safety using noninferiority (NI) design. Success was defined by composite negative cough stress test and subjective improvement in SUI using Patient Global Impression of Improvement at 36 months. Patient-reported outcomes of sexual function were assessed at baseline and 6, 12, 18, 24 and 36 months using Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12). Changes in sexual function were analyzed within and between groups. Outcomes for patients requiring surgical retreatment secondary to persistent incontinence, mesh-related complications, and voiding dysfunction were determined.

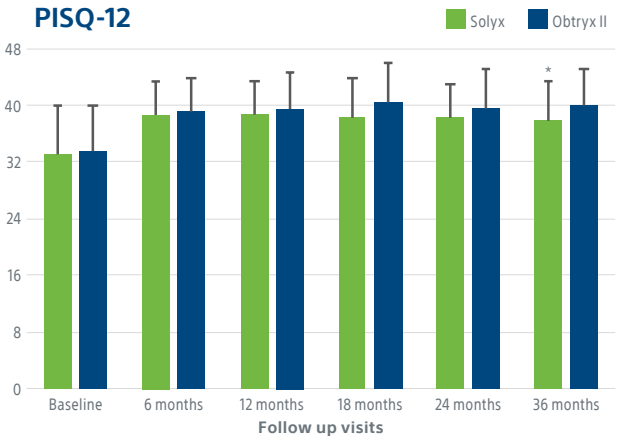
Results

Baseline patient characteristics were balanced using propensity score stratification (N=141 SIS, N=140 TMUS). Groups were similar in age, body mass index, and concomitant surgery performed (Table 1). Average length of follow-up was 30 months. Treatment success was 90.1% (91/101) in SIS and 89.3% (92/103) in TMUS in the per protocol analysis demonstrating NI at the preset margin (-1.3%,90% CI [-9.3%,6.6%]). Sexual activity was similar between groups (123/141 SIS,114/140 TMUS, P=0.18). Severity of urinary incontinence did not correlate with sexual activity. There was significant increase in the mean PISQ-12 score from baseline to 36 months for SIS and TMUS, indicating better sexual function at each follow-up visit. There were no significant differences seen in PISQ-12 scores between SIS and TMUS except at 36 months, where the difference was not clinically important (-2.5,95% CI [-4.7,0.2], Table 2). Among patients undergoing surgical retreatment (9/281,3%), improvement in sexual function was maintained after reoperation. De novo dyspareunia was rare following both treatments (SIS 1/141, TMUS 0/140, P=1.00).

Table 1: Demographics; (Intent-to-Treat Cohort)

	SIS		TMUS	
	Sexually Active (N=123)	Not Sexually Active (N=18)	Sexually Active (N=114)	Not Sexually Active (N=26)
Age, yrs	46.6±9.2 (123) (27.0, 46.0, 76.0)	66.6±11.3 (18) (42.0, 65.5, 88.0)	46.4±10.1 (114) (23.0, 45.0, 73.0)	60.0±11.9 (26) (40.0, 58.0, 84.0)
Body mass index	29.4±7.5 (123) (17.9, 27.9, 59.2)	30.6±5.7 (18) (19.8, 30.9, 47.4)	29.1±6.1 (114) (18.4, 28.0, 46.7)	32.2±6.7 (26) (20.9, 33.1, 49.3)
Race White	89.4% (110/123)	77.8% (14/18)	86.8% (99/114)	92.3% (24/26)
Hispanic or Latina	11.4% (14/123)	0.0% (0/18)	26.3% (30/114)	19.2% (5/26)
Smoker (current)	8.9% (11/123)	11.1% (2/18)	15.8% (18/114)	15.4% (4/26)
Diabetes	1.6% (2/123)	16.7% (3/18)	6.1% (7/114)	19.2% (5/26)
Peri- or Post-Menopausal	43.1% (53/123)	88.9% (16/18)	33.3% (38/114)	84.6% (22/26)
Estrogen use	20.3% (25/123)	33.3% (6/18)	14.0% (16/114)	15.4% (4/26)
Hysterectomy, prior	26.8% (33/123)	38.9% (7/18)	19.3% (22/114)	46.2% (12/26)
Urinary incontinence surgery, prior	0.0% (0/123)	5.6% (1/18)	1.8% (2/114)	3.8% (1/26)
Concomitant procedure	67.8% (82/121)	61.1% (11/18)	62.3% (71/114)	44.0% (11/25)
Vaginal Parity	2.1±1.3 (123) (0.0, 2.0, 6.0)	2.3±1.9 (18) (0.0, 2.0, 6.0)	2.4±1.4 (114) (0.0, 2.0, 6.0)	2.7±2.0 (26) (0.0, 3.0, 8.0)
Type of Prolapse				
Anterior Vaginal Wall Prolapse	47.2% (58/123)	44.4% (8/18)	41.2% (47/114)	30.8% (8/26)
Posterior Vaginal Wall Prolapse	35.0% (43/123)	33.3% (6/18)	36.8% (42/114)	26.9% (7/26)
Apical Prolapse	36.6% (45/123)	33.3% (6/18)	43.0% (49/114)	34.6% (9/26)

Numbers are % (Count/Sample Size) or mean ± SD (N) (min, median, max).



*Statistically significant at 0.05 level.

Table 2: Pelvic Impact Sexual Questionnaire (PISQ-12); (Intent-to-Treat Cohort)

	Treatment		Propensity Adjusted Treatment Difference	
Study Visit	SIS†	TMUS†	Estimate [95% CI]	p-value**
Baseline	33.3 ± 7.1(113) (13.0,35.0,47.0)	33.7 ± 6.5(103) (15.0,35.0,45.0)	-0.9 [-3.0 , 1.3]	0.425
6 months	38.9 ± 4.7(97) (22.0,40.0,46.0)	39.4 ± 4.8(93) (25.0,40.0,47.0)	-0.5 [-2.2 , 1.3]	0.603
12 months	39.0 ± 4.6(88) (25.0,40.0,46.0)	39.8 ± 5.2(90) (16.0,41.0,48.0)	-0.9 [-2.8 , 0.9]	0.318
18 months	38.5 ± 5.6(87) 15.0,39.0,46.0)	40.4 ± 5.3(90) (25.0,42.0,47.0)	-1.7 [-3.7 , 0.3]	0.093
24 months	38.5 ± 4.8(79) (24.0,40.0,46.0)	39.6 ± 5.3(82) (24.0,41.0,48.0)	-0.9 [-3.1 , 1.3]	0.421
36 months	37.9 ± 5.6(80) (22.0,39.0,45.0)	40.1 ± 5.2(77) (18.0,41.0,48.0)	-2.5 [-4.7 , -0.2]	0.031

† PISQ-12 has a range from 0-48 with higher scores indicating better sexual function.

** Baseline variables included in the propensity model: age, body mass index, race, ethnicity, smoker, diabetes, menopausal status, estrogen use, prior hysterectomy, prior urinary incontinence surgery, concomitant procedure, surgeon experience, baseline UDI, VAS, PFIQ, and other prior therapies including pelvic floor exercise and medication.

Conclusions

Patients have significant improvement in sexual function after SIS and TMUS surgery. De novo sexual pain is low after sling surgery.

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