PRESENTED AT

American Urogynecologic Society

ANNUAL CONGRESS

September 24-29, 2019 ▪ Nashville, Tennessee

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)

Author Block: Amanda B. White, MD, University of Texas, Dell Medical School, Austin, TX; Karyn S. Eilber, MD, Cedars- Sinai Medical Center, Los Angeles, CA; Jennifer T. Anger, MD, MPH, Cedars- Sinai Medical Center, Los Angeles, CA; Bruce S. Kahn, MD, Scripps Clinic, San Diego, CA; Joseph Schaffer, MD, University of Texas Southwestern Medical Center, Dallas, TX

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.

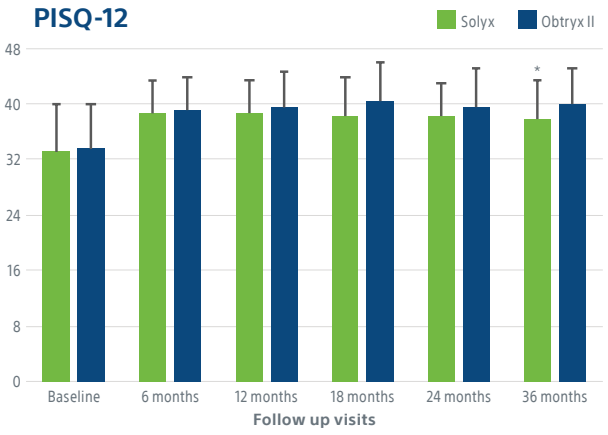
Results

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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Bench test results may not necessarily be indicative of clinical performance.

This study was funded by Boston Scientific, however, Boston Scientific had no role in study design, implementation, data analysis, or writing of the manuscript.

Complications cited in this summary are specific to this study.

The following adverse events have been reported due to suburethral sling placement, any of which may be ongoing, but are not limited to: As with all implants, local irritation at the wound site and/or a foreign body response may occur, Foreign body reaction may be acute or chronic, Pain (pelvic, vaginal, groin/thigh, suprapubic, dyspareunia) (acute or chronic), Dyspareunia, Tissue responses to the mesh implant could include: erosion into organs (urethra, bladder or other surrounding tissues); exposure/extrusion into the vagina, Mesh contact with urine via erosion/exposure/extrusion may result in stone formation, scarring/scar contracture, Necrosis, fistula formation (acute or chronic), inflammation (acute or chronic), Mesh contracture, Tissue contracture, Vaginal shortening or stenosis that may result in dyspareunia and/or sexual dysfunction, Pain with intercourse that may not resolve, Exposed mesh may cause pain or discomfort to the patient's partner during intercourse, Sexual dysfunction, including the inability to have intercourse. Like all foreign bodies, the mesh may potentiate an existing infection. Allergic reaction has been reported. Known risks of surgical procedures for the treatment of incontinence include: pain, ongoing pain (pelvic, vaginal, groin/thigh, suprapubic, dyspareunia), Severe, chronic pain, Apareunia, Leg weakness, Infection, De novo detrusor instability, Complete failure of the procedure/failure to resolve a patient's stress urinary incontinence, Voiding dysfunction (incontinence, temporary or permanent lower urinary tract obstruction, difficulty urinating, pain with urination, overactive bladder, and retention), Bruising, bleeding (vaginal, hematoma formation), Abscess, Vaginal discharge, Dehiscence of vaginal incision, Edema and erythema at the wound site, Perforation or laceration of vessels, nerves, bladder, urethra or bowel may occur during placement. The following additional adverse events have been reported for the Solyx SIS System: Dysuria, Hematuria. The occurrence of these events may require surgical intervention and possible removal of the entire mesh. In some instances, these events may persist as a permanent condition after surgical intervention or other treatment. Removal of mesh or correction of mesh-related complications may involve multiple surgeries. Complete removal of mesh may not be possible and additional surgeries may not always fully correct the complications.

Caution: Federal (US) law restricts this device to sale by or on the order of a physician trained in use of surgical mesh for repair of stress urinary incontinence. Refer to package insert provided with this product for complete Indications for Use, Contraindications, Warnings, Precautions, Adverse Events, and Instructions prior to using these products.

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. Information for use only in countries with applicable health authority registrations. Material not intended for use in France.

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Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
www.bostonscientific.com

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WH-667401-AA JUL 2021