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Study Title: A PROSPECTIVE PARALLEL COHORT, MULTI-CENTER STUDY OF THE SOLYX™ SINGLE INCISION SLING SYSTEM VS. THE OBTRYX™ II SLING SYSTEM FOR THE TREATMENT OF WOMEN WITH STRESS URINARY INCONTINENCE: PATIENT-REPORTED OUTCOMES AT 3 YEARS

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

Introduction and Objectives

Compare patient-reported outcomes (PROs) after single incision sling (SIS) and transobturator mid-urethral sling (TMUS).

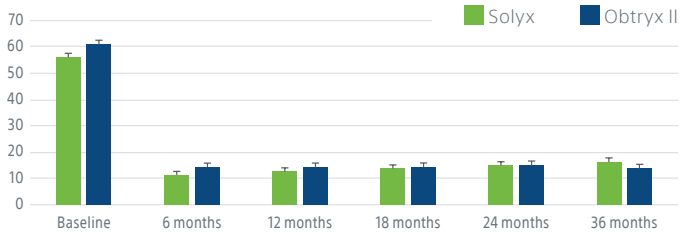
Methods

This is a planned secondary analysis of a prospective study comparing SIS to TMUS. Primary study aim was to compare efficacy and safety using a non-inferiority (NI) design to detect 15% difference in treatment success and 10% difference in safety. Treatment success was defined by composite objective measure (negative cough stress test) and subjective improvement in stress urinary incontinence (UI) using Patient Global Impression of Improvement (PGI-I) at 36 months. We collected validated PROs at baseline, 6, 12, 18, 24 and 36 months to quantify UI severity (Incontinence Severity Index (ISI)), symptom bother (Urogenital Distress Inventory (UDI-6)), disease-specific quality of life (QoL) impact (Urinary Impact Questionnaire (UIQ-7)), and generic QoL impact (PGI-I). PROs were analyzed within treatment groups as well as between groups.

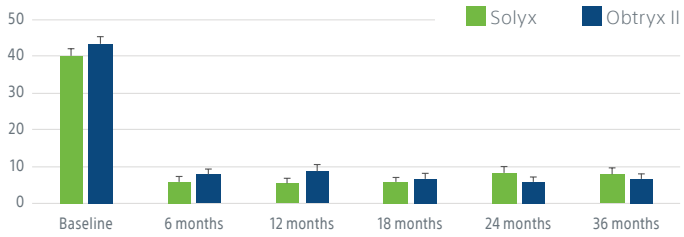
Results

Baseline characteristics were balanced after propensity score stratification (N=141 SIS, N=140 TMUS). Groups were similar in age (49.1±11.6 vs 48.9±11.7, P=0.4), body mass index (29.6±7.3 vs 29.7±6.3, P=0.9), and concomitant surgery (66.9% vs 59%, P=0.9). Average length of follow-up was 30 months. Treatment success was 90.1% (91/101) in SIS and 89.3% (92/103) in TMUS among available cases in per protocol analysis. Treatment difference was -1.3%, 90% CI [-9.3%, 6.6%], demonstrating NI at the pre-set margin. In both groups, serious adverse event (AE) rate (mesh-related complications) was 0.7%, and AE rates (dyspareunia, pelvic pain and urinary retention) were low. Participants had significant improvement in UI severity, disease-specific symptom bother and QoL impact, and improvements persisted through the study. PROs were similar between treatment groups in all assessments at 36 months.

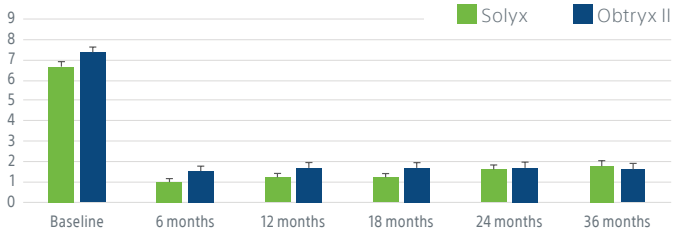
Urogenital Distress Inventory (UDI-6)



Urinary Impact Questionnaire (UIQ-7)



Incontinence Severity Index (ISI)



Patient Global Impression of Improvement (PGI-I)

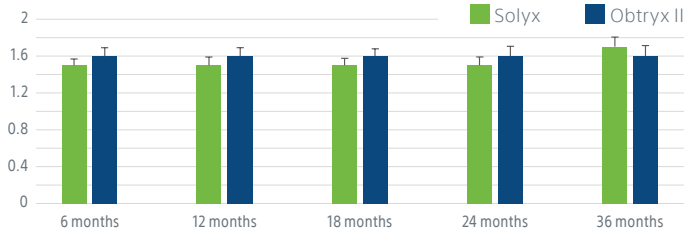


Table 1: Urogenital Distress Inventory (UDI), Intent to Treat

	Treatment		Unadjusted Treatment Difference		Propensity Adjusted Treatment Difference	
Visit	**Solyx†**	**Obtryx II†**	**Estimate [95% CI]**	**p-value**	**Estimate [95% CI]**	**p-value***
Baseline	56.0 ± 18.2(140) (5.6,55.6,100.0)	61.1 ± 19.6(138) (5.6,61.1,100.0)	-5.1 [-9.5 , -0.6]	0.026	1.6 [-3.4 , 6.5]	0.529
6 Months	11.1 ± 14.6(119) (0.0,5.6,61.1)	14.4 ± 16.6(129) (0.0,11.1,66.7)	-3.4 [-7.3 , 0.6]	0.093	-1.5 [-6.3 , 3.3]	0.541
12 Months	12.8 ± 15.2(106) (0.0,11.1,66.7)	14.1 ± 16.4(121) (0.0,11.1,66.7)	-1.3 [-5.4 , 2.9]	0.553	-0.4 [-5.6 , 4.7]	0.869
18 Months	13.8 ± 14.6(113) (0.0,11.1,72.2)	14.1 ± 16.6(118) (0.0,5.6,94.4)	-0.3 [-4.4 , 3.7]	0.873	1.2 [-3.7 , 6.2]	0.623
24 Months	14.7 ± 14.3(108) (0.0,11.1,61.1)	14.7 ± 17.4(112) (0.0,11.1,88.9)	-0.0 [-4.3 , 4.2]	0.993	0.1 [-5.1 , 5.4]	0.959
36 Months	15.9 ± 16.6(104) (0.0,11.1,83.3)	14.0 ± 16.7(108) (0.0,11.1,66.7)	1.8 [-2.7 , 6.3]	0.426	4.2 [-1.3 , 9.8]	0.135

† Numbers are mean ± SD (n) (min, median, max)

* 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.

Table 2: Incontinence Severity Index (ISI), Intent-to-Treat

	Treatment		Unadjusted Treatment Difference		Propensity Adjusted Treatment Difference	
Visit	**Solyx†**	**Obtryx II†**	**Estimate [95% CI]**	**p-value**	**Estimate [95% CI]**	**p-value***
Baseline	6.7 ± 2.9(140) (1.0,7.0,12.0)	7.4 ± 3.1(140) (0.0,8.0,12.0)	-0.7 [-1.4 , -0.0]	0.049	-0.6 [-1.5 , 0.2]	0.135
6 Months	1.0 ± 1.9(119) (0.0,0.0,9.0)	1.5 ± 2.8(129) (0.0,0.0,12.0)	-0.5 [-1.1 , 0.1]	0.117	-0.5 [-1.3 , 0.2]	0.151
12 Months	1.2 ± 2.0(106) (0.0,0.0,8.0)	1.7 ± 2.9(121) (0.0,0.0,12.0)	-0.5 [-1.2 , 0.2]	0.146	-0.5 [-1.3 , 0.4]	0.269
18 Months	1.2 ± 2.0(113) (0.0,0.0,9.0)	1.7 ± 2.8(118) (0.0,0.0,12.0)	-0.4 [-1.1 , 0.2]	0.169	-0.4 [-1.2 , 0.3]	0.240
24 Months	1.6 ± 2.3(108) (0.0,1.0,12.0)	1.7 ± 3.0(112) (0.0,0.0,12.0)	-0.1 [-0.8 , 0.6]	0.758	-0.0 [-0.9 , 0.8]	0.931
36 Months	1.8 ± 2.8(103) (0.0,1.0,12.0)	1.6 ± 3.1(108) (0.0,0.0,12.0)	0.3 [-0.5 , 1.1]	0.537	0.7 [-0.2 , 1.7]	0.138

† Numbers are mean ± SD (n) (min, median, max)

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Table 3: UIQ-7, Intent-to-Treat

	Treatment		Unadjusted Treatment Difference		Propensity Adjusted Treatment Difference	
Visit	**Solyx†**	**Obtryx II†**	**Estimate [95% CI]**	**p-value**	**Estimate [95% CI]**	**p-value***
Baseline	40.0 ± 23.0(140) (0.0,38.1,100.0)	43.5 ± 23.1(140) (0.0,42.9,100.0)	-3.5 [-8.9 , 2.0]	0.209	3.2 [-2.9 , 9.3]	0.304
6 Months	6.0 ± 16.1(119) (0.0,0.0,76.2)	7.9 ± 16.5(129) (0.0,0.0,81.0)	-1.9 [-6.0 , 2.2]	0.352	-1.8 [-6.8 , 3.3]	0.491
12 Months	5.5 ± 14.3(106) (0.0,0.0,71.4)	8.9 ± 20.5(121) (0.0,0.0,100.0)	-3.4 [-8.1 , 1.3]	0.152	-4.6 [-10.3 , 1.2]	0.117
18 Months	5.8 ± 12.8(113) (0.0,0.0,76.2)	6.8 ± 16.4(118) (0.0,0.0,100.0)	-1.0 [-4.8 , 2.8]	0.605	-1.3 [-5.9 , 3.3]	0.569
24 Months	8.4 ± 17.9(108) (0.0,0.0,90.5)	5.7 ± 14.1(112) (0.0,0.0,100.0)	2.7 [-1.6 , 7.0]	0.211	2.0 [-3.2 , 7.2]	0.450
36 Months	8.0 ± 18.1(104) (0.0,0.0,95.2)	6.5 ± 14.2(108) (0.0,0.0,71.4)	1.5 [-2.9 , 5.9]	0.492	3.4 [-2.0 , 8.8]	0.213

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Table 4: Patient Global Impression of Improvement (PGI-I), Intent-to-Treat

	Treatment		Unadjusted Treatment Difference		Propensity Adjusted Treatment Difference	
Visit	**Solyx†**	**Obtryx II†**	**Estimate [95% CI]**	**p-value**	**Estimate [95% CI]**	**p-value***
6 Months	1.5 ± 0.8(119) (1.0,1.0,5.0)	1.6 ± 1.0(129) (1.0,1.0,7.0)	-0.1 [-0.3 , 0.1]	0.423	-0.1 [-0.4 , 0.1]	0.350
12 Months	1.5 ± 0.9(106) (1.0,1.0,6.0)	1.6 ± 1.0(121) (1.0,1.0,7.0)	-0.0 [-0.2 , 0.2]	0.957	-0.1 [-0.3 , 0.2]	0.724
18 Months	1.5 ± 0.8(113) (1.0,1.0,5.0)	1.6 ± 0.9(117) (1.0,1.0,5.0)	-0.1 [-0.3 , 0.1]	0.536	-0.2 [-0.4 , 0.1]	0.175
24 Months	1.5 ± 0.9(108) (1.0,1.0,6.0)	1.6 ± 1.1(112) (1.0,1.0,7.0)	-0.1 [-0.4 , 0.2]	0.398	-0.1 [-0.5 , 0.2]	0.428
36 Months	1.7 ± 1.1(104) (1.0,1.0,6.0)	1.6 ± 1.2(108) (1.0,1.0,7.0)	0.0 [-0.3 , 0.3]	0.872	-0.0 [-0.4 , 0.4]	0.980

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Conclusions

Following SIS and TMUS, patients have significant improvement in PROs including UDI-6, ISI and UIQ-7 at 36 months, indicating disease-specific QoL improvement. Patients have a more positive impression of change in stress UI symptoms at each follow-up visit, indicating generic QoL improvement.

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.

Results from different clinical investigations are not directly comparable. Information provided for educational purposes only.

Caution: U.S. Federal 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.

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

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