

P R E S E N T E D A T

American Urological Association

■ A N N U A L C O N G R E S S ■

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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

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Introduction and Objectives

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

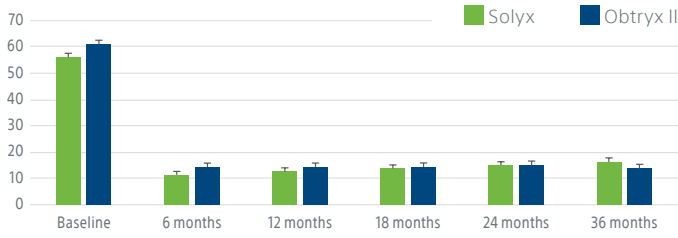
Methods

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.

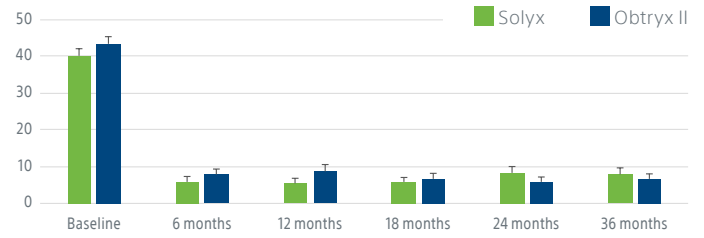
Results

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.

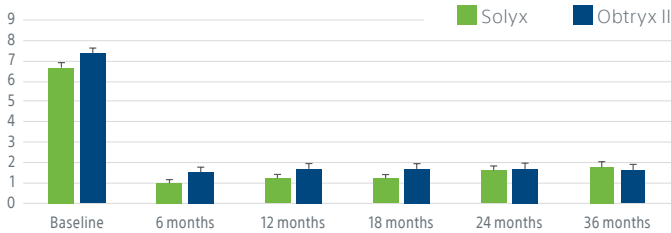
Urogenital Distress Inventory (UDI-6)



Urinary Impact Questionnaire (UIQ-7)



Incontinence Severity Index (ISI)



Patient Global Impression of Improvement (PGI-I)

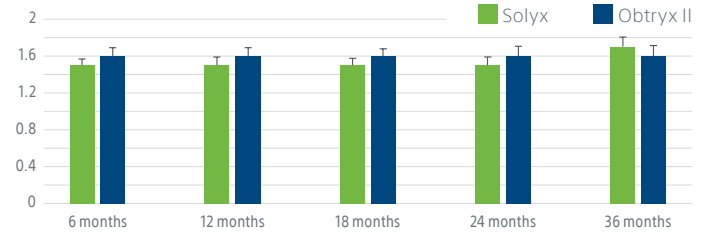


Table 1: Urogenital Distress Inventory (UDI), Intent to Treat

Visit	Treatment		Unadjusted Treatment Difference		Propensity Adjusted Treatment Difference	
	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

Visit	Treatment		Unadjusted Treatment Difference		Propensity Adjusted Treatment Difference	
	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)

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

Visit	Treatment		Unadjusted Treatment Difference		Propensity Adjusted Treatment Difference	
	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

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

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

Visit	Treatment		Unadjusted Treatment Difference		Propensity Adjusted Treatment Difference	
	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

† 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.

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.

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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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