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Study Title: PROSPECTIVE STUDY OF A SINGLE-INCISION SLING VERSUS A TRANSOBTURATOR SLING IN WOMEN WITH STRESS URINARY INCONTINENCE: 3-YEAR RESULTS

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Objective

To determine whether the Solyx™ single-incision sling is noninferior to the Obtryx II™ transobturator sling in efficacy and safety for treatment of stress urinary incontinence. This 522 post-market surveillance study has been designed in response to a U.S. Food and Drug Administration (FDA) request to evaluate improvement in stress urinary incontinence at 36 months following single-incision sling compared with baseline, as well as provide an assessment of mesh-related complications and subject-reported outcomes, relative to the transobturator sling control.

Study Design

This prospective, nonrandomized, parallel cohort, multicenter post-approval study enrolled subjects to receive single-incision sling or transobturator sling. Study sites were assigned to a cohort group based on documented competency with the cohort device. Patient follow-up was 36 months to compare efficacy and adverse events for non-inferiority. Inclusion criteria included stress predominant urinary incontinence, a positive cough stress test, and post-void residual ≤150 cc. Participants were ineligible if they had undergone previous stress urinary incontinence surgery or had a previous mesh complication. Primary endpoint was treatment success defined by composite negative cough stress test and subjective improvement in stress urinary incontinence using Patient Global Impression of Improvement at 36 months. Secondary endpoints included adverse events and indications for retreatment. Non-inferiority margins of 15% and 10% were prespecified for the primary efficacy and safety endpoints. Data analysis was performed using intent-to-treat and per-protocol methods. Due to the observational nature of the study, a propensity score methodology was applied to account for differences in patient and surgeon characteristics between treatment groups. The study design and variables to be included in the propensity score model were reviewed and approved by FDA reviewers before outcome analyses were performed.

Results

No evidence of imbalance in baseline characteristics was observed between groups after propensity score stratification in the 281 subjects. Estimated blood loss in mL (72.3±92 vs. 73.1±63.9), time to spontaneous void in days (1.1±2 vs. 0.8±2.8), and time to discharge in days (0.7±0.7 vs. 0.6±0.6) were similar between SIS and TMUS, respectively. SIS group was NI to the TMUS group in composite treatment success with both ITT and PP analyses. At 36 months, ITT analysis showed treatment success of 90.4% in the SIS group and 88.9% in the TMUS group (P = 0.93), Figure 1. At 36 months, mesh related complications were similar between groups (mesh exposure: 2.8% vs. 4.3%, P = 0.54; mesh erosion: 0.0% vs. 0.7%, P = 0.50). SAE including pain during intercourse (0.7% vs. 0%, P = 1.00), pelvic pain (0.7% vs. 0%, P = 1.00), and urinary retention (2.8% vs. 4.3%, P =0.54) were similar between groups, Figure 2.

						Propensity adjusted		
Missing data handling	**Analysis cohort**	**Single-Incision Sling**		**Transobturator mid-urethral sling**		**Estimate [90% CI]**		**p-value[a]**
Available cases	Intent-to-treat	90.4%	(94/104)	88.9%	(96/108)	-0.4%	[-8.2%, 7.4%]	0.933
	Per protocol	90.1%	(91/101)	89.3%	(92/103)	-1.3%	[-9.3%, 6.6%]	0.782
Missing data = treatment failure	Intent-to-treat	66.7%	(94/141)	68.6%	(96/140)	-3.4%	[-13.3%, 6.5%]	0.570
	Per protocol	67.4%	(91/135)	69.7%	(92/132)	-4.1%	[-14.1%, 5.9%]	0.496
Multiple imputation	Intent-to-treat	89.4%	(126/141)	88.9%	(124/140)	-1.0%	[-8.8%, 6.8%]	0.839
	Per protocol	89.3%	(121/135)	89.7%	(118/132)	-2.4%	[-10.2%, 5.4%]	0.617

CI, confidence interval

[a] Noninferiority evaluation is through confidence interval. P-value tests for inequality.

Figure 1: Composite Treatment Success at 36 Months, Intent-to-treat (N=281)

	Single Incision Intent-to-Treat Subjects (N=141)			**Obturator Intent-to-Treat Subjects (N=140)**		
Adverse Events (coded with MedDRA Preferred Term)	**Events**	**Proportion of Subjects with ≥1 Events**		**Events**	**Proportion of Subjects with ≥1 Events**	
Device extrusion (mesh exposure)	4	2.8%	(4/141)	7	5.0%	(7/140)
Dyspareunia	1	0.7%	(1/141)	0	0.0%	(0/140)
Medical device site reaction (mesh erosion)	0	0.0%	(0/141)	1	0.7%	(1/140)
Pelvic Pain	1	0.7%	(1/141)	0	0.0%	(0/140)
Urinary retention	4	2.8%	(4/141)	6	4.3%	(6/140)

Figure 2: Summary of Selected Adverse Events — MedDRA Outcome, Intent-to-treat (N=281)

Conclusions

Single-incision sling was not inferior to transobturator sling for long-term treatment success of stress urinary incontinence. The rates of serious adverse events were acceptably low and similar between groups.

White AB, Kahn BS, Gonzalez RR, Rosamilia A, Anger JT, Eilber KS, Schaffer JI. Prospective study of a single-incision sling versus a transobturator sling in women with stress urinary incontinence: 3-year results. *Am J Obstet Gynecol.* 2020 Oct;223(4):545.e1-545.e11. doi: 10.1016/j.ajog.2020.03.008. Epub 2020 Mar 14. PMID: 32184149.

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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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