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Study 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

Author Block: Amanda B. White, MD[a], Jennifer Anger, MD[b], Karyn Eilber, MD[c], Bruce S. Kahn, MD[d], Ricardo Gonzalez, MD[e], Anna Rosamilia, MD[f]

a. Department of Women's Health, University of Texas at Austin, Dell Medical School, Austin, TX, USA
b. Department of Surgery, Division of Urology, Cedars-Sinai Health System, Los Angeles, CA, USA
c. Department of Obstetrics and Gynecology, Scripps Clinic, San Diego, CA, USA
d. Department of Urology, Houston Methodist Hospital, Houston, TX, USA
e. Department of Women's Health, Monash Medical Centre and Cabrini Hospital, Melbourne, Australia

Objective

Limited data exist regarding sexual function after single-incision sling surgery. We compared sexual function 36 months post-operatively between patients undergoing single-incision (SIS) and transobturator sling (TMUS) for treatment of stress urinary incontinence.

Study Design

Assessment of sexual function was a planned secondary objective of this prospective, multi-center study that enrolled women to Solyx single-incision sling or Obtryx II transobturator sling. Primary study aim was to compare efficacy and safety using noninferiority design 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 were determined.

Baseline 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. Average length of follow-up was 30 months. Baseline sexual activity was similar (123/141 SIS, 114/140 TMUS, P=0.18). Severity of urinary incontinence did not correlate with baseline sexual activity. Mean PISQ-12 scores increased significantly from baseline to 36 months for both groups, indicating better sexual function at each visit. There were no significant differences in PISQ-12 scores between groups except at 36 months, where the difference was small (-2.5, 95% CI [-4.7,0.2]). Among patients undergoing surgical retreatment (9/281, 3%), improvement in sexual function was maintained. De novo dyspareunia was rare following both treatments (SIS 1/141, TMUS 0/140, P=1.00).

Pelvic Impact Sexual Questionnaire (PISQ-12)

	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.

Conclusions

Patients have significant and sustained improvement in sexual function after single incision sling and transobturator sling up to 3 years. De novo sexual pain is low after sling surgery.

The results in this summary are specific to this study. This study was sponsored and funded by Boston Scientific.

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. Refer to package insert provided with this product for complete Indications for Use, Contraindications, Warnings, Precautions, Adverse Events, and Instructions prior to using this product.

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
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Marlborough, MA 01752
www.bostonscientific.com

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