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Solyx™ Single-Incision Sling

Clinical Support Summaries

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Solyx™ Single-Incision Sling

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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.

Objective

The aim of this study was to determine whether the use of the Solyx Single-Incision Sling (SIS) was noninferior to the traditional Obtryx II Transobturator Mid-Urethral Sling (TMUS) in efficacy and safety at 36 months.

Overview

- Study Attributes:
  - Prospective, non-randomized
  - 36-month follow-up
  - Multi-center (21 sites)
  - 281 patients
- Inclusion Criteria: Predominant stress urinary incontinence (SUI) greater than urgency incontinence (UI), confirmed with cough stress test (CST), and post-void residual ≤ 150 cc. Concomitant pelvic organ prolapse (POP) repair allowed.
- Exclusion Criteria: Recurrent urinary tract infections (UTIs), previous mesh-related complications, or prior procedure for SUI
- Primary Endpoints: An assessment of improvement in SUI at 36 months
  - Treatment success was defined by a composite score combining an objective measure (a negative cough stress test) plus a self-reported improvement in SUI symptoms (Patient Global Impression of Improvement [PGI-I])
- Secondary Endpoints:
  - Rates of serious adverse events
  - Mesh exposure/erosion
  - Retreatment
  - Quality of life assessments

Conclusion

Solyx SIS **was not inferior** to Obtryx II TMUS **for long-term treatment success** of stress urinary incontinence. The rates of **serious adverse events were acceptably low and similar between groups.**

Key Findings

- **Solyx SIS was non-inferior to Obtryx II TMUS** in composite treatment success.
- At 36 months, ITT analysis showed composite treatment success of 90.4% in the SIS group and 88.9% in the TMUS group **(Table 1)**.
- Objective success at 36 months (measured by negative CST) was similar between the SIS and TMUS groups **(94.2% SIS vs. 91.7% TMUS)**.
- Self-reported improvement in SUI symptoms on the PGI-I was similar between the SIS and TMUS groups.
- **Secondary endpoints were not significantly different between SIS and TMUS groups.**
  - The SIS was noninferior to TMUS for safety, given the low and comparable rates of adverse events. **(Table 2)**.
  - The proportion of SIS subjects with an adverse event was 10.6% compared with 15.7% for TMUS subjects.
  - Serious adverse events had even lower rates and were similarly comparable. These included pain during intercourse (0.7% vs. 0%), pelvic pain (0.7% vs. 0%), and urinary retention (2.8% vs. 4.3%). Mesh-related complications were also similar between groups (mesh exposure: 2.8% vs. 5.0%.
- There were no differences in mean **operative time, blood loss, and time to hospital discharge.**

Key Findings (continued)

Table 1: Composite Treatment Success at 36 Months, from Available Cases

				Propensity adjusted	
Missing data handling	**Analysis cohort**	**SIS**	**TMUS**	**Estimate [90% CI]**	**p-value***
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

When missing data is treated as treatment failure, the SIS group again demonstrated noninferiority to the TMUS group in treatment success.

CI, Confidence interval
* Noninferiority evaluation is through confidence interval. P-value tests for inequality

Table 2: Summary of Selected Adverse Events — MedDRA Outcome, 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)
Pelvic Pain	1	0.7% (1/141)	0	0.0% (0/140)
Urinary retention	4	2.8% (4/141)	6	4.3% (6/140)

* This includes 1 mesh erosion event that occurred in the TMUS group.

Comments

- Overall, the rates of adverse events seen in this study were lower than previously reported. This may be due to a relatively young and healthy study population.
  - In addition, not only were investigators required to demonstrate competency in placing the respective study device, they were also high-volume surgeons with lower complication rates than lower volume surgeons.
- "Transition to SIS, as shown in our study maintains the benefits of TMUS placement with reduced neurologic sequelae. It also confers the benefit of markedly less mesh volume, which is desirable considering the negative attention transvaginal mesh has received. The origination of a less invasive procedure, combined with the possibility of performing SIS under local anesthesia in the office, provides value and reduced cost in the surgical treatment of female SUI."

Acknowledgements
This study was sponsored by Boston Scientific; the sponsor assembled a team of collaborators to design this study in accordance with the FDA 522 mandate and provided statistical analysis of data. Authors independently completed the writing of the report and submitted article for publication.

Author Disclosures
A.B.W.: Boston Scientific: investigator (522 Solyx), consultant; B.S.K.: Boston Scientific: investigator (522 Solyx); Johnson & Johnson: expert witness; R.R.G.: Boston Scientific: investigator (522 Solyx), consultant, advisory board member, speaker's bureau; A.R.: Boston Scientific: investigator (522 Solyx, investigator- initiated research); Coloplast: investigator; Allergan: speaker; Ethicon: expert witness; J.T.A.: Boston Scientific: investigator (522 Solyx), expert witness; K.S.E.: Boston Scientific: investigator (522 Solyx), expert witness, advisory board; Allergan: consultant and speaker; Ethicon: expert witness; and J.I.S.: Boston Scientific: investigator (522 Solyx), McGraw- Hill: editorial; Astellas: speakers bureau.

Complications cited in this summary are specific to this study.

White AB, et al.
Solyx™ Single-Incision Sling vs. Obtryx™ II Sling

522 Postmarket Surveillance Study of the Solyx Single-Incision Sling System: Patient-Reported Outcomes at 36 Months – Secondary Analysis

White AB, Eilber KS, Anger J, Kahn BS, Schaffer JI. 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. Abstract. *Eur Urol Suppl.* 2019 Mar;18(1):e1370-1. doi: 10.1016/s1569-9056(19)30992-3.

Objective

The aim of this study was to compare PROs after single-incision sling (SIS) and transobturator mid-urethral sling (TMUS).

Overview

- This study was a planned secondary analysis of a prospective study comparing a single-incision sling (SIS) to a transobturator mid-urethral sling (TMUS)
- Study Attributes:
  - Prospective, non-randomized
  - 36-month follow-up
  - Multi-center (21 sites)
  - 281 patients
- Inclusion Criteria: Predominant stress urinary incontinence (SUI) greater than urgency incontinence (UI), confirmed with cough stress test (CST), and post-void residual ≤ 150 cc. Concomitant pelvic organ prolapse (POP) repair allowed.
- Exclusion Criteria: Recurrent urinary tract infections (UTIs), previous mesh-related complications, or prior procedure for SUI
- Primary Study Aim: To compare efficacy and safety using a noninferiority (NI) designed to detect 15% difference in treatment success and 10% difference in safety
- Aim of this Secondary Analysis: To collect and analyze validated patient-reported outcomes (PROs) at baseline, 6, 12, 18, 24 and 36 months. Included:
  - ISI – Incontinence Severity Index
  - UDI-6 – Urogenital Distress Inventory
  - UIQ-7 – Urinary Impact Questionnaire
  - PGI-I - Patient Global Impression of Improvement

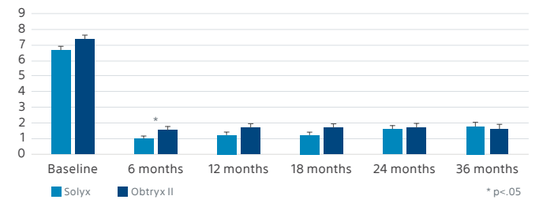
Conclusion

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

Key Findings

- 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.**

Figure 1: Incontinence Severity Index (ISI)



Key Findings (continued)

Figure 2: Urogenital Distress Inventory (UDI-6)

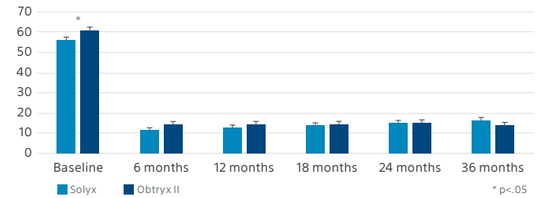
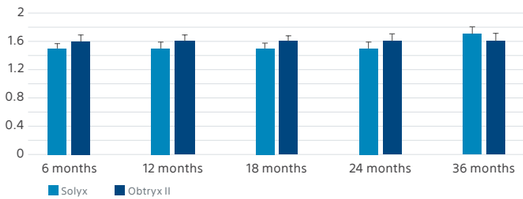
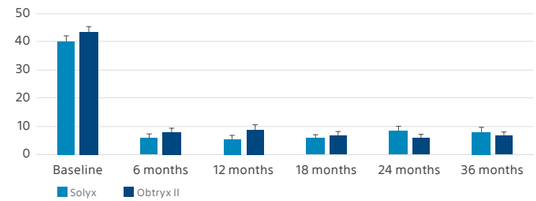


Figure 3: Patient Global Impression of Improvement (PGI-I)



* Statistically significant difference with p<.05

Figure 4: Urinary Impact Questionnaire (UIQ-7)



Comments

- The following PROs were analyzed within treatment groups as well as between groups:
  - ISI: measure of UI severity – 2 questions, lower score is better
  - UDI-6: measure of UI symptom bother – 6 questions, lower score is better
  - UIQ-7: measure of disease-specific quality of life impact – 7 questions, lower score is better
  - PGI-I: measure of generic quality of life impact – 1 question, lower score is better

Acknowledgements
This study was sponsored by Boston Scientific; the sponsor assembled a team of collaborators to design this study in accordance with the FDA 522 mandate and provided statistical analysis of data. Authors independently completed the writing of the report and submitted article for publication.

Author Disclosures
A.B.W.: Boston Scientific: investigator (522 Solyx), consultant; K.S.E.: Boston Scientific: investigator (522 Solyx), expert witness, advisory board; Allergan: consultant and speaker; Ethicon: expert witness; J.A.: Boston Scientific: investigator (522 Solyx), expert witness; B.S.K.: Boston Scientific: investigator (522 Solyx); Johnson & Johnson: expert witness; and J.I.S.: Boston Scientific: investigator (522 Solyx), McGraw- Hill: editorial; Astellas: speakers bureau.

Complications cited in this summary are specific to this study.

White AB, et al.
Solyx™ Single-Incision Sling vs. Obtryx™ II Sling

522 Postmarket Surveillance Study of the Solyx Single-Incision Sling System: Female Sexual Function Following Sling Surgery – Secondary Analysis

White AB, Anger JT, Eilber K, Kahn BS, Gonzalez RR, Rosamilia A. Female sexual function following sling surgery: a prospective parallel cohort, multi-center study of the Solyx™ Single Incision Sling System versus the Obtryx™ II Sling System (FDA-mandated 522 results at 36 months). *J Urol.* 2021 Sep;206(3):696-705. doi: 10.1097/JU.0000000000001830.

Objective

The aim of this study was to compare sexual function 36 months postoperatively between patients undergoing SIS (Solyx) and TMUS (Obtryx II) for treatment of SUI.

Overview

- Study Attributes: This is a planned secondary analysis of a prospective study comparing a single-incision sling (SIS) to a transobturator mid-urethral sling (TMUS)
  - Prospective, non-randomized
  - 36-month follow-up
  - Multi-center (21 sites)
  - 281 patients
- Inclusion Criteria: Predominant stress urinary incontinence (SUI) greater than urgency incontinence (UI), confirmed with cough stress test (CST), and post-void residual ≤ 150 cc. Concomitant pelvic organ prolapse (POP) repair allowed.
- Exclusion Criteria: Recurrent urinary tract infections (UTIs), previous mesh-related complications, or prior procedure for SUI
- Primary Study Aim:
  - To compare efficacy and safety using a noninferiority (NI) design to detect 15% difference in treatment success and 10% difference in safety
- Aim of this Secondary Analysis:
  - To assess patient-reported outcomes of sexual function at baseline, 6, 12, 18, 24 and 36 months using Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12)

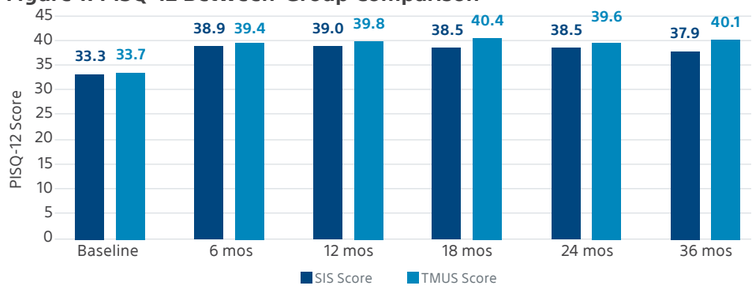
Conclusion

Patients have **significant improvement in sexual function** after SIS and TMUS. **De novo sexual pain is low** after sling surgery.

Key Findings

- Baseline sexual activity was similar between groups:
  - SIS: 87.2% [123/141]
  - TMUS: 81.4% [114/140]
- For both treatment groups, there was a **significant increase (improvement) in mean PISQ-12 score from baseline to 36 months**, indicating better sexual function following the sling procedure (Table 1).
- At every time point, there was an **improvement in sexual function** from baseline as measured by the PISQ-12 in **both groups.**
  - This improvement was maintained from the 6-month assessment to 36 months
- When PISQ-12 scores were compared between the SIS and TMUS groups, there were **no significant differences in the mean scores between the treatment groups** at any time point except at 36 months where the difference was small (Figure 1, Table 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).

Figure 1: PISQ-12 Between-Group Comparison



Key Findings (continued)

Table 1: PISQ-12 Change from Baseline

	Treatment Arm				Propensity Adjusted Treatment Difference on Change from Baseline		
	SIS		TMUS				
Visit	Score	Change from Baseline	Score	Change from Baseline	Estimate	[95% CI]	p Value
Baseline	33.3 +/- 7.1	-	33.7 +/- 6.5	-	-	-	-
6 mos	38.9 +/- 4.7	5.0 +/- 5.6	39.4 +/- 4.8	5.6 +/- 7.1	-0.1	[-2.4, 2.1]	0.906
12 mos	39.0 +/- 4.6	4.7 +/- 5.6	39.8 +/- 5.2	6.0 +/- 6.6	-0.7	[-3.0, 1.6]	0.557
18 mos	38.5 +/- 5.6	4.1 +/- 5.5	40.4 +/- 5.3	6.4 +/- 6.7	-1.6	[-3.7, 0.6]	0.152
24 mos	38.5 +/- 4.8	2.9 +/- 5.4	39.6 +/- 5.3	5.9 +/- 6.6	-2.5	[-4.9, -0.0]	0.049
36 mos	37.9 +/- 5.6	3.0 +/- 5.8	40.1 +/- 5.2	6.9 +/- 6.6	-4.0	[-6.5, -1.5]	0.002

Table 2: PISQ-12 Between-Group Comparison

	Treatment Arm				Propensity Adjusted Treatment Difference on Change from Baseline		
	SIS		TMUS				
Visit	Score	SD	Score	SD	Estimate	[95% CI]	p Value
Baseline	33.3	7.1	33.7	6.5	-0.9	[-3.0, 1.3]	0.425
6 mos	38.9	4.7	39.4	4.8	-0.5	[-2.2, 1.3]	0.603
12 mos	39.0	4.6	39.8	5.2	-0.9	[-2.8, 0.9]	0.318
18 mos	38.5	5.6	40.4	5.3	-1.7	[-3.7, 0.3]	0.093
24 mos	38.5	4.8	39.6	5.3	-0.9	[-3.1, 1.3]	0.421
36 mos	37.9	5.6	40.1	5.2	-2.5	[-4.7, -0.2]	0.031

Comments

- The PISQ-12 is a validated short form used to assess improvement in sexual function and desire in women undergoing therapy for POP and urinary incontinence.
  - It is important to note that the PISQ-12 measures sexual function only among sexually active heterosexual women.
- While the study was sponsored by industry, the study design, outcomes, and analysis were approved and reviewed regularly by the FDA over the 36-month study period.

Acknowledgements
This study was sponsored by Boston Scientific; the sponsor assembled a team of collaborators to design this study in accordance with the FDA 522 mandate and provided statistical analysis of data. Authors independently completed the writing of the report and submitted article for publication.

Author Disclosures
A.B.W: Boston Scientific: investigator (522 Solyx), consultant; J.T.A.: Boston Scientific: investigator (522 Solyx), expert witness; K.S.E.: Boston Scientific: investigator (522 Solyx), expert witness, advisory board; Allergan: consultant and speaker; Ethicon: expert witness; B.S.K.: Boston Scientific: investigator (522 Solyx); Johnson & Johnson: expert witness; R.R.G.: Boston Scientific: investigator (522 Solyx), consultant, advisory board member, speaker's bureau; A.R.: Boston Scientific: investigator (522 Solyx); Coloplast: investigator; Allergan: speaker; Ethicon: expert witness.

Complications cited in this summary are specific to this study.

Serels S, et al.
Long-Term Follow-Up of Solyx™ SIS

Multicenter, Retrospective Study: Long-Term Follow-Up of the Solyx Single-Incision Sling in the Treatment of Female Stress Urinary Incontinence

Serels S, Douso M. Long term follow up of the Solyx Single Incision Sling in the treatment of female stress urinary incontinence (SUI). *Open J Urol.* 2014 Feb;4(2):13-7. doi: 10.4236/oju.2014.42003.

Objective

The goal of this study was to retrospectively assess the long-term safety and efficacy of the Solyx™ Single-Incision Sling System in women with SUI.

Overview

- Study Attributes:
  - Retrospective with prospective follow-up
  - Utilized chart reviews and follow-up phone questionnaires
  - Mean follow-up of 43 months
  - Multicenter, utilizing 2 locations
  - 69 patients
- Inclusion Criteria: SUI due to urethral hypermobility
- Exclusion Criteria: Evidence of detrusor instability
- Primary Endpoints: Utilized both subjective and objective metrics
  - Sling Efficacy
    - Based on reported dryness by questionnaire and standing cough stress test
  - Satisfaction
    - Based on reported happiness with procedure and willingness to do it again
- Other Outcomes:
  - Procedural Complications
  - Implant-related Adverse Events

Conclusion

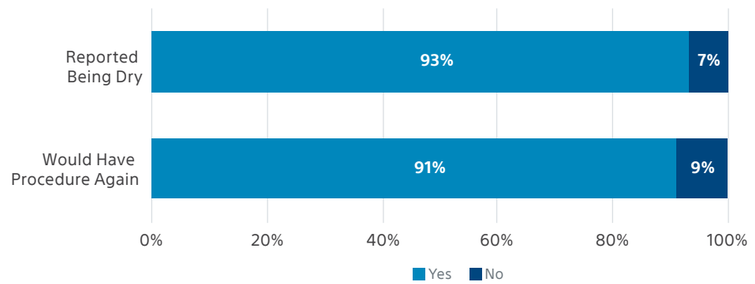
This study indicated that the **Solyx SIS is a safe, effective and less-invasive option** for patients requiring SUI surgery, and that these **results are sustainable,** considering the average follow-up period of 43 months.

- This **efficacy** appears to be **comparable to the retropubic and obturator approaches, with minimal tissue disruption providing minimal postoperative discomfort.**
- **Lack of pain, retention and significant complications,** along with the ease of placement makes **Solyx SIS a safe and effective procedure** to correct SUI.

Key Findings

- **64/69 of patients were subjectively dry and satisfied** with their outcome while **63/69 of patients said they would have the procedure again.**

Figure 1: Subjective Efficacy & Satisfaction



Key Findings (continued)

- **Cough stress test correlated 1:1** with patients who were **subjectively dry.**
- 4 cases of de novo urge incontinence emerged, along with 2 reports of transient retention.
- **No serious adverse events** were reported.

Figure 2: Cough Stress Test Results

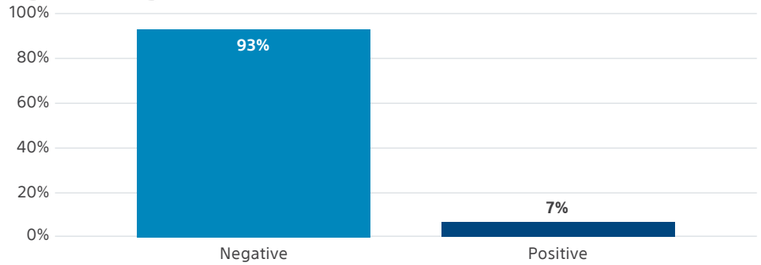


Table 1: Complications Reported

Complications	
Bladder, Bowel, Vessel, Nerve Perforations	0
Mesh Erosions	0
Mesh Extrusions	0
Implant-attributed Pain	0

Comments

- Single-incision slings are appealing for their minimal invasiveness and potential for decreased morbidity.
  - Less invasive than TVT or TOT slings.
  - Retropubic and transobturator slings have favorable results but require 3 incisions and blind trocar passage.
  - Blind needle passage may pose the risk of visceral and vascular damage.

Acknowledgements
This paper was supported by a restricted educational grant from Boston Scientific.

Disclosures
The authors declare that they have no conflict of interest.

Complications cited in this summary are specific to this study.

Multicenter, Retrospective Study: Preliminary Findings with the Solyx Single-Incision Sling System in Female Stress Urinary Incontinence

Serels S, Douso M, Short G. Preliminary findings with the Solyx™ single-incision sling system in female stress urinary incontinence. *Int Urogynecol J.* 2010 May;21(5):557-61.

Objective

The aim of this study was to assess retrospectively the short-term safety and efficacy of the Solyx™ Single-Incision Sling in women with SUI.

Overview

- Study Attributes:
  - Retrospective
  - Mean follow-up of 6.5 months
  - Multicenter, utilizing 3 locations
  - 63 patients
- Inclusion Criteria: SUI diagnosis using subjective symptoms and objective clinical signs, including CST and urethral hypermobility of >30°
- Exclusion Criteria: None listed
- Primary Endpoints: Dryness on the basis of objective and subjective outcomes
  - Objective: Employed a cough stress test with 300ml of sterile water in the bladder
  - Subjective: Asked patients if they were completely dry, with 'yes' or 'no' response
- Other Endpoints:
  - Procedure complications
  - Implant-attributed pain

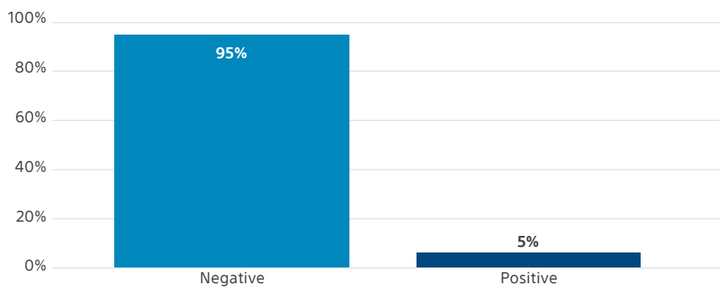
Conclusion

- The **reduced level of complications, high continence rates** and **ease of application** with the Solyx SIS make it attractive.
- Minimal steps in the procedure will **facilitate competence** with the technique and **assist in reproducibility.**

Key Findings

- **95% of patients were dry** based on both subjective and objective assessments. (Figure 1)
  - **Subjective** responses directly **corresponded to objective outcomes.**

Figure 1: Cough Stress Test Results



Key Findings (continued)

- 3.2% of patients (2/63) experienced transient urinary retention.
  - **Resolved spontaneously** in both cases.
- **No complications were reported** at 6.5-month mean follow-up.

Table 1: Complications Reported at 6.5-month Mean Follow-up

Complications	
Bladder, Bowel, Vessel, Nerve Perforations	0
Mesh Erosions	0
Mesh Extrusions	0
Implant-attributed Pain	0

Comments

- Some physicians perceive single-incision slings as being "tighter" than their retropubic and transobturator counterparts. This belief is based on perceived placement and not on tensioning tests.
- A previous cadaver study by the same author, Serels, had 30 experienced physicians assess sling placements of SIS, TO and RP slings in a blinded fashion, evaluating placement method, tension and location of the sling.[1]
- Results showed SIS as having:
  - Most correct tension.
    - 73% describing SIS as 'just right.'
    - 33% for retropubic.
    - 47% for obturator.
  - Most correct midurethral positioning.
    - 83% for SIS.
    - 50% for retropubic.
    - 67% for obturator.

1. Serels S. Cadaveric assessment of synthetic mid-urethral sling placement. Presented at the 30th World Congress of the Société Internationale d'Urologic Meeting, 1 – 5 November, 2009, Shanghai, China

Acknowledgements
This paper was supported by a restricted educational grant from Boston Scientific.

Disclosures
The authors received honoraria for lecturing on behalf of Boston Scientific Corporation.

Complications cited in this summary are specific to this study.

Serels S, et al.
Preliminary Results on Safety and Efficacy of Solyx™ SIS

Multicenter, Prospective Study: Safety and Efficacy of the Solyx Single-Incision Sling for the Treatment of Stress Urinary Incontinence: Preliminary Results

Serels S, Nosseir SB, Lind LR, et al. Safety and efficacy of the Solyx single-incision sling for the treatment of stress urinary incontinence: preliminary results. *UroToday Int J.* 2011 Feb;4(1). doi:10.3834/uij.1944-5784.2011.02.05

Objective

The objective of this study was to assess the short-term safety and efficacy of the Solyx™ Single-Incision Sling System.

Overview

- Study Attributes:
  - Prospective, nonrandomized study
  - 12-week follow-up
  - Multicenter, utilizing 2 locations
  - 19/21 patients finished follow-up
- Inclusion Criteria: SUI due to urethral hypermobility
- Exclusion Criteria: Evidence of detrusor instability, recurrent SUI or fixed urethra
- Primary Endpoints: Device-related adverse events. Peri- and postoperative complications
- Secondary Endpoints:
  - Sling efficacy based on a standing cough stress test
  - Sling tolerability based on patient satisfaction through validated questionnaires (UDI-6 and I-QOL)

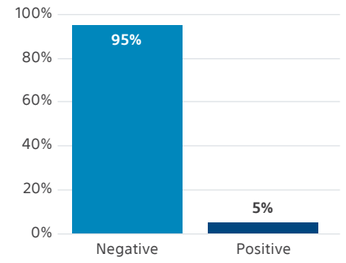
Conclusion

- Solyx SIS appears to be a **safe and effective procedure** to correct SUI **based on:**
  - **Lack of postoperative pain, urinary retention and significant complications** experienced by patients.
  - **Ease of placement** for the surgeon.
- Solyx SIS provided **excellent continence rates**, leading to **improved quality of life.**
- Single incision with **minimal tissue disruption** led to **minimal postoperative discomfort.**

Key Findings

- **94.7%** (18/19) had **negative standing CST** and **no longer wore pads** at 12 weeks.
- 1 patient developed de novo urgency but saw resolution through medication.
- **No differences in success** rates of those **with and without concomitant procedures.**
  - 10/19 had concomitant procedures.
- **Statistically significant improvement** from preoperative scores **in both UDI-6 and I-QOL questionnaires** (Table 1).
  - No significant changes between weeks 6 and 12.
- **100%** (19/19) of patients **reported satisfaction with their outcomes** 12 weeks after surgery (Table 2).

Figure 1: Cough Stress Test Results



Key Findings (continued)

Table 1: Pre- and Postoperative I-QOL and UDI-6 Scores

	Presurgery (n=21)		6-weeks Postsurgery (n=21)			12-weeks Postsurgery (n=19)		
Test	**Mean**	**Range**	**Mean**	**Range**	***P***	**Mean**	**Range**	***P***
I-QOL, score	74	29-105	102.1	62-110	<.0001	102.4	89-110	.90
UDI-6, score	50	16.7-77.7	28.7	0-44.4	<.0001	8.2	0-27.8	.84

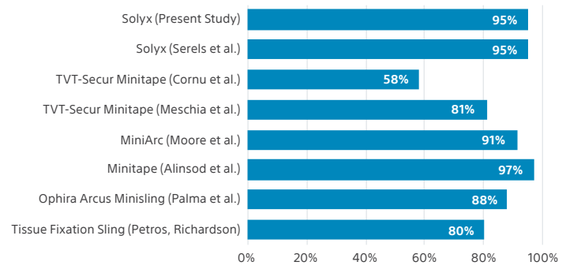
Table 2: Patient-Reported Satisfaction 12 Weeks Postoperative

Patient-Reported Satisfaction (12-Weeks)		
Completely Satisfied	5	26.3%
Very Satisfied	10	52.6%
Satisfied	3	15.8%
Somewhat Satisfied	1	5.3%
Not Satisfied	0	0.0%

Comments

- Questionnaires Details:
  - UDI-6 – "Urogenital Distress Inventory" with higher scores indicating greater disability.
  - I-QOL – "Incontinence Quality of Life" with higher scores indicating a greater impact on quality of life.
- Single-incision slings are appealing for their minimal invasiveness and potential for decreased morbidity.
  - Retropubic and transobturator slings have favorable results but require 3 incisions and blind trocar passage, potentially causing visceral and/or vascular damage.
- Several past studies have investigated the efficacy of single-incision sling systems. Methodologies – including primary endpoints and follow-up times, among other factors – vary. Results can be found in Figure 2.

Figure 2: Success Rates - Previous Studies[1-7]



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Author Disclosures
Scott Serels and Lawrence R. Lind – speakers and consultants for Boston Scientific Corporation.

Complications cited in this summary are specific to this study.

Lau HH, et al.
SIS vs. TOT in Overweight and Obese Women

Success Rates of Single-Incision vs. Transobturator Slings in Overweight/Obese Patients at 3 Years

Lau HH, Enkhtaivan S, Su TH, et al. The outcome of a single-incision sling versus trans-obturator sling in overweight and obese women with stress urinary incontinence at 3-year follow-up. *J Clin Med.* 2019 Jul 25;8(8):1099. doi: 10.3390/jcm8081099.

Objective

This study aimed to analyze the objective and subjective cure rates achieved by single-incision slings in overweight and obese women as compared to trans-obturator slings.

Overview

- Study Attributes:
  - Retrospective study
  - Median follow-up of 37 months
  - Single center, 2 experienced surgeons
  - 217 total patients
    - 106 SIS – 72 overweight, 34 obese
    - 111 TOT – 71 overweight, 40 obese
- Inclusion Criteria: Received SIS or TOT, BMI 25.0 – 30.0 kg/m^2, BMI >30 kg/m^2
- Exclusion Criteria: Recurrent SUI, concomitant surgery, mixed incontinence
- Primary Endpoints:
  - Objective success – no urine leakage during stress test in the filling phase of urodynamics
  - Subjective success – the sum of subjective cure and improvement rates
  - Subjective cure – no leakage after surgery
- SIS procedures included Solyx™ Single-Incision Sling System and MiniArc™ Sling; TOT utilized Gynecare™ TVT-O

Conclusion

- Found **no significant differences in cure rates** between SIS and TOS **in both overweight and obese women.**
- SIS showed worse urine leakage and incontinence symptoms in obese group but **had less surgical and wound pain.**

Key Findings

- There were **no significant differences** regarding **subjective and objective cure rates, de novo symptoms, and postoperative quality of life in overweight** group.
- **Objective and subjective outcomes were also comparable** between devices in **obese patients,** with **no statistically significant differences.**

Table 1: Objective & Subjective Cure Rates

Objective & Subjective Cure Rates			
Overweight	**SIS (n=72)**	**TOT (n=71)**	***p***
Objective	64 (89%)	62 (87%)	0.488
Subjective	66 (92%)	64 (91%)	0.489
Obese	**SIS (n=34)**	**TOT (n=40)**	***p***
Objective	26 (76%)	32 (80%)	0.465
Subjective	27 (79%)	34 (85%)	0.372

  - Incontinence-related symptom distress (UDI-6) and postoperative 1-hour pad tests were worse in the **obese** group for SIS. (Table 2)
- Study found **no statistically significant differences between SIS and TOT in objective and subjective cure rates** in women with a BMI ≥ 25 kg/m^2.
- **Operation time and postoperative pain** scores were **both significantly better** in SIS patients.
- Neither group had long-term adverse effects nor mesh extrusion.

Key Findings (continued)

Table 2: Quality of Life Outcomes

Quality of Life Outcomes			
Overweight	**SIS**	**TOT**	***p***
UDI-6	2.7 +/- 2.1	3.2 +/- 3.3	0.473
IIQ-7	2.1 +/- 3.9	3.3 +/- 4.8	0.257
PISQ-12	37.8 +/- 19.1	36.2 +/- 16.3	0.896
Obese	**SIS**	**TOT**	***p***
UDI-6	6.7 +/- 2.0	3.0 +/- 3.3	<0.001
IIQ-7	6.1 +/- 7.9	6.2 +/- 5.9	0.573
PISQ-12	30.7 +/- 17.1	29.1 +/- 16.0	0.479

Comments

- Subjective questionnaires were used to assess quality of life outcomes:
  - UDI-6 – "Urogenital Distress Inventory" with higher scores indicating greater disability.
  - IIQ-7 – "Incontinence Impact Questionnaire" with higher scores indicating a worsening impact of SUI on quality of life.
  - PISQ-12 – "POP/UI Sexual Function Questionnaire" with higher scores indicating better sexual function.

Acknowledgments
None

Disclosures
The authors declare that they have no conflict of interest.

Complications cited in this summary are specific to this study.

Lo TS, et al.
Solyx™ SIS – Efficacy and Risk Factors for Failure

Objective and Subjective Cure Rates at 12 Months

Lo TS, Shailaja N, Chua S, et al. Evaluation of clinical outcome and risk factors for failure of single-incision midurethral short tape procedure (Solyx tape) for stress urinary incontinence. *J Minim Invasive Gynecol.* 2019 May-Jun;26(4):688-94. doi: 10.1016/j.jmig.2018.07.013.

Objective

The aim of this study was to evaluate the objective cure of pure SUI patients using the Solyx™ Single-Incision Sling System, with subjective cure and identification of risk factors that cause failure as the secondary aim.

Overview

- Study Attributes:
  - Retrospective case-series
  - 12-month follow-up for clinical outcomes; 21.4-month mean follow-up for complications
  - Single center, utilizing a tertiary referral center
  - 113 patients
- Inclusion Criteria: Patients with urodynamic stress incontinence (USI) without needing concurrent procedures that opted to use Solyx SIS
- Exclusion Criteria: Subjective SUI without urine leak on UDS test, POP > stage II, neurogenic bladder dysfunction, PVR >100 mL
- Primary Outcomes:
  - Objective cure rate, defined as the absence of urine leakage upon CST and a 1-hour pad test weight <2 g
- Secondary Outcomes:
  - Subjective cure rate, defined as a negative response to UDI-Question 3 (no leakage on coughing, sneezing, or laughing)
  - Identification of the different risk factors of cure failure

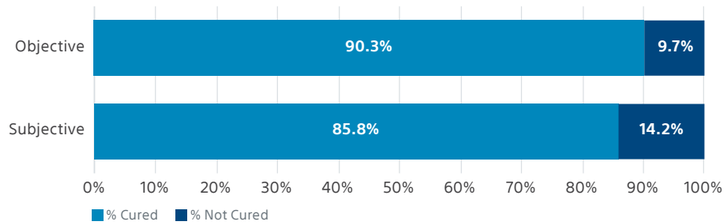
Conclusion

Solyx SIS is a safe and effective treatment option for women with SUI, **showing high objective and subjective cure rates** with a **low incidence of complications** 1 year after treatment. The identified independent **risk factors** for failure are related to **poor urethral function and previous pelvic reconstructive surgery.**

Key Findings

- **90.3% (102/113) of patients were objectively cured at 12-month follow-up** (Figure 1).
- **85.8% (97/113) were subjectively cured in same follow-up period** (Figure 1).
- **SIS Failure was significantly associated with various risk factors. These included:**
  - Prior prolapse surgery
  - Prior anti-SUI surgery
  - Neurogenic disease
  - Constipation
  - ISD
  - Preoperative MUCP (maximum urethral closure pressure) below 40 cm H_2O

Figure 1: Objective & Subjective Cure Rates



- **Postoperative questionnaire** scores **relating to quality of life** were all **improved from preoperative responses** with statistical significance (Table 1).

Key Findings (continued)

- No perioperative or postoperative complications were reported as well as no complaints of pain in relation to the sling placement (Table 2).

Table 1: Pre- and Post-operative Questionnaire Scores

Pre- and Postoperative Questionnaire Scores			
n=113	**Pre-**	**Post-**	***p***
UDI-6	11.7 +/- 3.3	4.1 +/- 2.5	< 0.001
IIQ-7	13.7 +/- 2.7	4.2 +/- 2.4	< 0.001
PISQ-12 (n=41)	23.1 +/- 3.2	27.1 +/- 3.3	< 0.001

Table 2: Other Measures & Outcomes

Other Measures & Outcomes	
Perioperative Complications	0
Postoperative Complications	0
Implant-attributed Pain	0

Comments

- "The high cure rate of Solyx SIS could be attributed to the self-fixing anchoring tip. The anchoring tip has a 3-spike design that measures 1.3 cm in length and 0.4 cm in width, which may have provided a stronger grip and placement in the obturator internus muscle."

Acknowledgements
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Disclosures
The authors declare that they have no conflict of interest.

Complications cited in this summary are specific to this study.

Tucker I.
Single-Incision Slings – Audit of Solyx™ SIS and MiniArc™ Sling

Review of Effectiveness and Complications: Single-Incision Slings – Audit of a Decade of Use

Tucker I. Single incision slings-audit of a decade of use. Poster. *Aust N Z J Obstet Gynaecol*. 2018;58:79-81.

Objective

The aim of this study was to present a decade of use of SIS procedures and review the effectiveness and complications.

Overview

- Study Attributes:
  - Retrospective case series
  - Mean follow-up of 3.97 years, ranging from 0.5 to 9 years
  - Single center
  - 283 patients
- Inclusion Criteria: All SIS procedures performed by the author between 2007 and October 2016
- Exclusion Criteria: Not reported
- Endpoints:
  - Efficacy based on average reported success using a visual analog scale (VAS)
  - Pain based on patient-reported outcomes on 0-10 scale
  - Complications such as mesh exposure and need for replacement were also tracked

Conclusion

- SIS procedures are extremely **successful medium- to long-term,** with **minimal complications and minimal pain.**
- The few failures were **successful with repeat SIS.**
- **Solyx™ Single-Incision Sling System and MiniArc™ Sling** appear to have **similar success rates.**

Key Findings

- **Solyx** and **MiniArc** sling systems had comparable (Table 1):
  - **Subjective success rates**
  - **Pain rates**

Table 1: Procedure Outcomes

Procedure Outcomes			
	Solyx	**MiniArc**	**Total**
Cases	38	245	283
Avg Follow Up (Yrs)	2	4	3.97
Avg Success (VAS %)	93.6	95	95
Avg Pain (0 - 10)	0.5	0.5	0.5

- **Solyx SIS achieved 98% success in** GSI (genuine stress incontinence) patients without OAB and/or ISD.
- **Minimal complications** occurred.
  - 4 cases of mesh exposure in sulcus (Figure 1)
  - 6 cases required repeat surgery, all of which were then successful (Figure 2)
- Postoperative **pain was minimal, averaging just 0.5 on 10-point scale.**
  - Only 6 patients reported pain up to 2 when SIS was the sole procedure
- **All** patients **reported they "would do it again."**

Key Findings (continued)

Figure 1: Cases With & Without Mesh Exposure

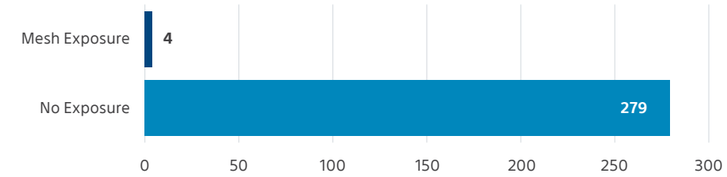
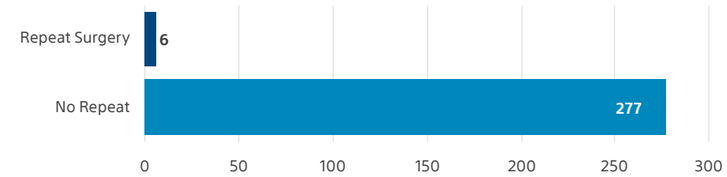


Figure 2: Cases With & Without Repeated Procedures



Comments

- Initial studies suggested success rates for SIS procedures were below that of other midurethral sling procedures; however, more recent studies following a slight modification of the technique have shown very acceptable success rates.
  - Many agree initial studies improperly placed SISs in relation to the midurethral tissue.
  - Solyx SIS and other SIS procedures require mesh placement that is more 'snug' around the urethra as opposed to the 'tension-free' spacing used in RMUS procedures.
- At this stage, most of the techniques in current practice have proven success and safety, but retropubic procedures carry the risk of bowel perforation, vessel injury, increased risk of bladder perforation and increased postoperative pain and voiding difficulties.
- As with all surgical procedures, adequate training and credentialing are essential.

Acknowledgements
None

Disclosures
The authors declare that they have no conflict of interest.

Complications cited in this summary are specific to this study.

Khandwala S, Cruff J.
Solyx™ SIMUS by DISST as an Office-based Procedure

Patient-Reported Outcomes and Negative Standing Provocative Stress Test at 6 Months

Khandwala S, Cruff J. Single-incision midurethral sling by the dynamic intraoperative standing sling technique as an office-based procedure: a pilot study. *Urology.* 2021 Mar;149:34-9. doi: 10.1016/j.urology.2020.11.020.

Objective

The aim of this study was to assess the safety, feasibility, and success of performing the Solyx™ Single-Incision Mid-Urethral Sling System (SIMUS) in an office-based setting with local anesthesia, with 6 months follow-up.

Overview

- Study Attributes:
  - Prospective case-series
  - 6-month follow-up
  - Single center
  - 20 patients
- Inclusion Criteria: Stress urinary incontinence (SUI) and urethral hypermobility, American Society of Anesthesiologists Class I/II, ability to stand during surgery
- Exclusion Criteria: American Society of Anesthesiologists Class ≥ III, demonstrated concomitant urgency incontinence and required concurrent procedures
- Endpoints:
  - Objective efficacy measured via a negative standing provocative stress test
  - Subjective efficacy utilized validated questionnaires
  - Postoperative complications
  - Surgical pain diary
  - Return to work/activities
  - Overall satisfaction

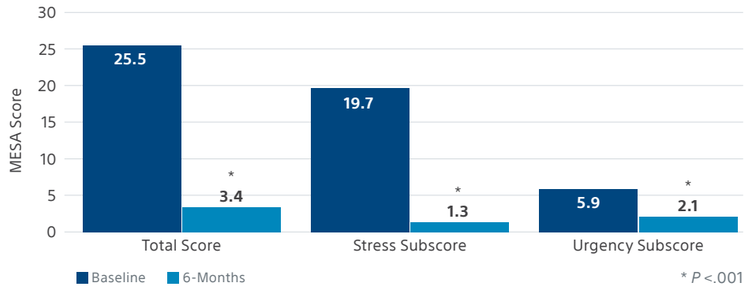
Conclusion

It appears **safe and feasible to perform Solyx SIMUS by the dynamic intraoperative standing sling technique (DISST) in an office setting.** Patients were **completely dry** and **reported significant subjective improvements 6 months from surgery.**

Key Findings

- **All 20 subjects had negative standing provocative stress tests at 6-month follow-up.**
- At 6 months, there were statistically **significant mean improvements in all 3 subjective questionnaires.**
  - **MESA** Scores – Medical, Epidemiologic, and Social Aspects of Aging

Figure 1: MESA Questionnaire Scores in Pure SUI

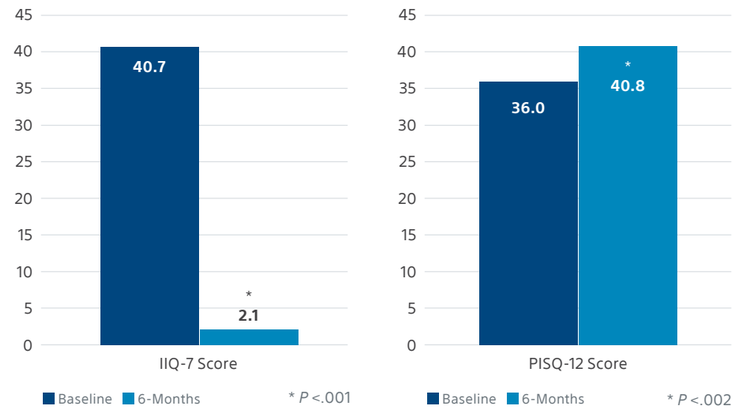


  - **IIQ-7** Scores – Incontinence Impact Questionnaire
  - **PISQ-12** Scores – POP/UI Sexual Function Questionnaire
- **85% voided spontaneously** immediately following surgery. 15% (3/20) required clean intermittent self-catheterization (CISC), but **halted use by post-operative day 1, 5, and 13.**

Key Findings (continued)

- **No complications or injuries reported.**
  - **Mean daily pain** scores were **all significantly decreased** from the day of surgery aside from post-operative day 1
  - Majority of subjects returned to work and normal activities **within a median of 1-2 days**
- **85%** said their condition was **"very much better"** while 15% said "much better" when asked to rate their SUI symptoms compared to before treatment.
- Separate analysis showed no difference in objective and subjective outcomes between obese (BMI ≥ 30 kg/m²) and nonobese women.

Figures 2 & 3: IIQ-7 and PISQ-12 Scores



Comments

- Questionnaires Details
  - MESA ranges from 0 – 45, with higher scores representing worse incontinence.
  - IIQ-7 ranges from 0 – 100, with higher scores indicating a worsening impact of SUI on quality of life.
  - PISQ-12 ranges from 0 – 48, with higher scores indicating better sexual function.
- Aside from procedure and device-specific benefits and outcomes, outpatient/office-based procedures are associated with a cost savings of over 35%, and with the ongoing COVID-19 pandemic, more patients are looking to stay away from hospitals. Thus, the ability to do an in-office procedure may be appealing.

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

Disclosures
The authors declare that they have no conflict of interest.

Complications cited in this summary are specific to this study.

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Potential Risks for Mid-Urethral Slings:

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.

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