Original Article

Comparison of Clinical Efficacy and Urodynamic Changes Using Single-incision Slings (MiniArc® vs. Solyx™) for the Treatment of Female Stress Urinary Incontinence

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Abstract

Objective: To compare the clinical efficacy and urodynamic parameter changes between the MiniArc and the Solyx sling for the treatment of female urodynamic stress incontinence (USI).

Materials and Methods: One-hundred and thirty (MiniArc n = 79, BS-Solyx n = 51) patients were included in this study. Cough stress test (ST), pad test (PT), Incontinence Impact short form Questionnaire (IIQ-7), Urogenital Distress Inventory six-item questionnaire (UDI-6), Sexual Questionnaire-Short Form (PIS-Q), and urodynamic parametric changes were assessed to determine objective and subjective outcomes following the procedure. Objective cure was defined as negative ST and PT <2 g and subjective cure was defined as "No" to the answer of UDI-6 Question #3. Predictors of surgical failure were also determined.

Results: All Solyx users, as opposed to 91.1% of MiniArc patients, obtained objective cure at postoperative 3 months (P = 0.042). No significant difference in subjective cure rates (93.7% vs. 90.2% at 3-months (P = 0.513); 89.9% vs. 80.4% at 1 year for Solyx and MiniArc patients, respectively (P = 0.126)) and improvement scores in UDI-6 and IIQ-7 were observed. The Solyx group incurred more *de novo* urgency (17.6% vs. 6.3% at 3 months (P = 0.042); 23.5% vs. 7.6% at 1 year (P = 0.01)). Both procedures yielded significant decrements in maximal urethral closure pressure (P < 0.001) and average flow rate (P = 0.015). The preoperative PT and sling type were strong predictors of surgical failure, where the Solyx tape reported lower odds (odds ratio = 0.174, P = 0.02) compared to the MiniArc sling.

Conclusion: Single-incision mini-slings are safe and effective treatment for female USI. The Solyx SIS demonstrated superiority over the MiniArc in this study based on its higher objective cure rate and lower risk for surgical failure.

Keywords: Efficacy, MiniArc, single incision slings, solyx, stress incontinence, urodynamic changes

Introduction

Stress urinary incontinence, described as involuntary leakage of urine following increase of abdominal pressure as in sneezing, coughing, and laughing, is associated with a negative impact of quality of life and everyday functioning for women of all ages. It is estimated to affect 10%–40% of the female population aged 15–64 years and has an even higher incidence after 65 years of age in the Western world.[1-3]

While mid-urethral sling (MUS) has earned its place as the gold standard for surgical treatment of stress urinary incontinence, more promising sling designs have been developed to capture all the qualities of an ideal MUS sling: minimally invasiveness, adjustability, better fixation system, less operation time and postoperative pain, safety, and

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favorable complication profile.[4] Both MiniArc® (American Medical Systems, Minnetonka, MN) and the Solyx™ single incision sling (SIS) system (Boston Scientific Corporation, Marlborough, MA) were the third generation of vaginal tapes, also known as single incision mini-slings (SIMS). Unlike its predecessors, MiniArc utilizes self-fixating tips and penetrates obturator foramen through a single incision, minimizes tissue damage and avoids potential organ damage associated with the retropubic route, and incurs less procedural time and pain.[5] Past studies of the MiniArc described a decent range of success rate (69.1%–91.4%),[6] good reproducibility, and a favorable objective cure of 90.6% after 1 year in the literature, which was comparable with the results for conventional mid-urethral tape.[7]

As compared to the MiniArc, the Solyx SIS comprises a delivery device and a wider mesh assembly consisting of a polypropylene anchoring tip at each distal end, which provides limited adjustability.[8] As a result, less attempts of readjustment may be warranted to preserve the integrity of the tissue in its caressing path. However, microadjustability also implies a steeper learning curve for the operator to tackle the technique to properly insert this "one take" device. The technique for placing this sling has been standardized to permit reproducible placement into the obturator internus muscle, with optimized tension as demonstrated in a cadaver study by Serels.[9] In the literature, Solyx SIS was found to have a high postoperative continence rate of 95% with minimal perioperative or postoperative complications at a mean of 6.5 months follow-up,[8] which makes the Solyx tape an attractive alternative option for treatment of SUI. While these mini-tapes have reported noninferiority to transobturator slings in terms of safety, effectiveness, and objective cure rate for the treatment of SUI demonstrated in Maturana's randomized controlled trial in 2019,[10] there are few reports of their postoperative effects on the clinical outcomes and urodynamic changes. Presently, diverse designs of SIMS from different companies are commercially available. Scant evidence supports the routine use of either the MiniArc or the Solyx SIS system in clinical practice for treating women with pure SUI.

The objective of this retrospective study is to compare the clinical outcomes and urodynamic changes between two well-established SIS, MiniArc and Solyx devices. Furthermore, we seek to interpolate our results to determine the predictors of failure following an SIS procedure.

Materials and Methods

This study was a retrospective observational study conducted by the Division of Urogynecology and Reconstructive Pelvic Surgery, Changhua Christian Hospital, a large tertiary referral center located in Changhua, Taiwan. This study was approved by the Changhua Christian Hospital Institutional Review Board on Human Subjects Research (CCH IRB No.: 171117). We have obtained the written consent from all participants.

Patients with clinical diagnosis of SUI from January 2015 to May 2018 were included. The inclusion criteria include age >18 years, clinical SUI or urodynamic stress incontinence (USI), and absence of associated neurological diseases. Exclusion criteria include findings suggestive of detrusor overactivity, pregnancy, acute cystitis, previous anti-SUI surgery, vaginal laser treatment within the past 1 year, gynecologic malignancy, and inability to complete requisite follow-ups. Patients with clinically demonstrated USI regardless of the type and symptomatic involuntary urinary leak refractory to conservative therapy meet the indication for surgical placement of SIS slings in this study. All surgical procedures were performed by the same senior urogynecologist to minimize potential experience or procedure-related inter-operator variances. Both MiniArc and Solyx devices are freely selected by patients and are not covered by the Bureau of National Health Insurance in Taiwan. There was no recommendation made for either slings, regardless of the patients' medical or physical conditions or preoperative urodynamic readings. Allocation of patients to slings was arbitrary and based entirely on individual's preference. To that extent, selection bias may be minimal. However, as MiniArc officially declared withdrawal from the market worldwide on March 9th, 2016, enrollment for patients undergoing MiniArc placement terminated on the aforementioned date and yielded only a total of 79 patients in the MiniArc group whom completed the requisite follow-ups during the study period. All procedures were performed in the dorsal lithotomy position. All patients were given prophylactic preoperative intravenous antibiotics and underwent surgery under general anesthesia.

Both MiniArc and Solyx tapes were inserted according to the original methods described by Debodinance[11] and Serels, respectively.[12] To conjure the correct amount of tension, a right angle Pean was placed in the center of the sling at the incision site to mimic a snug-fit before final fixation. Cystoscopy was performed on each patient following the sling insertion to make sure patients were free from urethral and bladder injury. A urinary catheter was inserted before the sling implantation and removed 2 days after surgery. The postvoid residual urine (PVR) was then measured twice. In cases of voiding difficulty (i.e., >100 mL residual urine), hospitalization was prolonged until a PVR <100 mL was obtained. In the case when an injury of the urethra or bladder occurred, a urinary catheter may be placed for a week or two and removed after healing.

Preoperative evaluations included a detailed history, physical examination, cough stress test (ST), a 1-hour pad test (PT),

and PVR measured using a bladder scan; preoperative urodynamic studies conform to the standardized protocol by International Continence Society, which included static and dynamic urethral pressure profiles, uroflowmetry, and urethrocystometry.[13] Before intervention, and at the 3-month postoperative follow-up, the patients completed two validated quality-of-life questionnaires, Urogenital Distress Inventory six-item questionnaire (UDI-6) and Incontinence Impact short form Questionnaire (IIQ)-7.[14] The IIQ-7 and UDI-6 were scored according to the established protocols. The Sexual Questionnaire (PIS-Q)[15] was only completed by patients with sexual activity. On the operative and the following day, subjects were asked by the study coordinator to rate their pain on a ten-point numeric visual analog scale (VAS).

Postoperative follow-up visits were scheduled at 1 week, and 3, 6, and 12 months. Charts produced from the study were reviewed both subjectively and objectively. All relevant peri-and postoperative complications were documented. Urodynamic testing, PVR, PT, and ST were performed postoperatively at 3 months. Patients were defined as "objectively cured" when they fulfilled either a negative cough ST or an 1-h PT weigh <2 g. After 3 months, the subjective outcomes were collected via telephone interviews by an experienced nurse using the UDI-6, IIQ-7, and PIS-Q questionnaires. Patients were defined as "subjectively cured" when they responded negatively to the third question on the UDI-6, "Do you experience urine leakage related to physical activity, coughing, or sneezing?"

Statistical analysis was performed using the Student's *t*-test for parametric and nonparametric continuous variables, and the Chi-square test or Fisher's exact test for the categorical variables. Paired *t*-test or McNemar test was used to examine within-group improvement at different time points. The investigators wish to assess whether there are differences in surgical outcome by age, parity, body mass index (BMI), prior hysterectomy, preoperative PT result and maximal urethral closure pressure (MUCP), sling type. Thus, multiple logistic regression analysis was employed to determine the regression coefficient, odds ratio (OR), and corresponding *P* value for each supposed predictor that contributed to the surgical failure, which was defined by either a postoperative PT heavier than or equal to 2 g, or a positive cough ST. All data were analyzed using the IBM SPSS Statistics for Windows, Version 22.0 (IBM Corp., Armonk, NY, USA); a $P < 0.05$ was considered statistically significant.

Results

Of 130 enrolled patients, 79 (60.8%) underwent a MiniArc and 51 (39.2%) underwent a Solyx tape procedure. All patients successfully followed through the study protocol and completed follow-up within the given timeframe. The patient demographics and characteristics are depicted in Table 1. Both groups shared similar baseline features, with the comparable percentage of patients undergoing single incisions sling alone, or had concomitant hysterectomy or vaginal anterior-posterior wall repair.

There were few complications in either group [Table 2], with no occurrence of any major intraoperative complications (bladder and urethra injury), nor postoperative complications (i.e. mesh erosion). Both groups were free from acute urinary retention (defined as residual urine volume >100 ml over 24 h) or prolonged urinary retention requiring sling release throughout the study period. Albeit insignificant, we saw a trend of less immediate postoperative pain in the Solyx group compared to the MiniArc group (11.8% vs. 25.3% at day 1, respectively, $P = 0.059$). However, there were significantly more cases of *de novo* urgency accruing over the follow-up visits from 3 to 12 months postsurgery in the Solyx group compared to the MiniArc group (17.6% vs. 6.3% at 3-mo, $P = 0.042$; 23.5% vs. 7.6% at 12-mo, respectively, $P = 0.010$).

Both groups showed significant improvement in objective and subjective outcomes at the postoperative follow-up period [Table 3]. This study demonstrated slightly better performance of the Solyx sling in objective outcomes, with a 92.2% negative cough ST at 3 months after surgery compared to 81% observed in the MiniArc group, $P = 0.079$. The Solyx group also demonstrated greater success than the MiniArc group in the 1-hour PT at 3 months postsurgery (0.07 ± 0.3 g vs. 0.7 ± 2.3 gm, respectively, $P = 0.013$), and higher objective cure rate (100% vs 91.1%, respectively, $P = 0.042$) [Table 3].

Subjective outcomes were recorded at 3 months and during the most recent postoperative telephone interview [Table 3]. Improvement scores of UDI-6, IIQ-7, and PISQ were calculated; of which, a point is earned if an improvement was observed postsling insertion, no points earned if no change, and 1 point subtracted if deteriorated symptoms were seen. Both groups illustrated postsurgery improvements in intra-group analysis. When comparing the two SIMS, the MiniArc group yielded a better UDI-6 mean of improvement score ($P = 0.003$ at 3-mo, $P = 0.002$ at 1-year), while better improvement score of IIQ-7 was noted for the Solyx group ($P < 0.001$ at 3-mo and 1-year). There was no significant difference in improvement rate between the groups during the study period. There was no substantial difference in subjective cure rate found between the two groups.

The urodynamic changes after sling surgery [Table 4] revealed a significant decrease in the MUCP in both groups ($P < 0.05$). When looking at mini-slings as a whole, both average flow rate (AVG) and MUCP decreased after

Table 1: Patient demographics and main characteristics

	MiniArc (*n*=79), *n* (%)	Solyx (*n*=51), *n* (%)	*P*
Age (years)	54.6±8.3	55.1±10.3	0.746
BMI (kg/h2)	24.7±3.3	25.0±3.0	0.523
Prior hysterectomy	15 (19.0)	5 (9.8)	0.156
Preoperative 1 h PT (g)	18.5±16.7	20.9±22.7	0.499
Negative ST	5 (6.3)	4 (7.8)	0.737
Concomitant hysterectomy	11 (13.9)	4 (7.8)	0.289
Concomitant AP repair	7 (8.9)	6 (11.8)	0.590
Single incision sling alone	68 (86.1)	45 (88.2)	0.751
Mean period of follow up (months)	11.4±8.0	13.1±7.7	0.242

P by Student's *t*-test or Chi-square test when applicable. Data are presented as *n* (%) or mean±SD. SD: Standard deviation, AP repair: Anterior and posterior colporrhaphy, BMI: Body mass index, PT: Pad test, ST: Stress test

Table 2: Comparison of the intra- and post-operative complications

	MiniArc (*n*=79)			Solyx (*n*=51)			*P*
	Intra- and postoperative immediate	Postoperative (3 months)	Postoperative (12 months)	Intra- and postoperative immediate	Postoperative (3 months)	Postoperative (12 months)	
Urinary tract infection	3 (3.8)	0	0	3 (5.9)	0	0	0.679[a]
Pain (VAS≥3, day 1)	20 (25.3)	-	-	6 (11.8)	-	-	0.059[a]
Pain (VAS≥3, day 2)	1 (1.3)	-	-	1 (2.0)	-	-	1.000[a]
Urinary retention	0	0	0	0	0	0	-
De novo urgency	0	5 (6.3)	6 (7.6)	0	9 (17.6)	12 (23.5)	0.042[b]*, 0.010[b]*
Bladder perforation	0	-	-	0	-	-	-
Urethra injury	0	-	-	0	-	-	-
De novo dyspareunia	-	0	0	-	0	0	-
Mesh erosion	-	0	0	-	0	0	-

*Statistically significant *P* (*P*<0.05), [a]*P* of complications resulted from using MiniArc as compared to that of Solyx tapes at intra- and immediately postoperation, [b]*P* of complications resulted from using MiniArc as compared to that of Solyx tapes at postoperative 3 and 12 months, -: Not applicable or not available. *P* by Chi-square test or Fisher's exact test when applicable. Data are presented as *n* (%).VAS: Visual analog score, with ten-point Numeric Pain Scale

treatment ($P < 0.05$). The Solyx group had a lower baseline MUCP (55.6 ± 28.2 vs. 67.6 ± 28.9, $P = 0.021$), but the amount of MUCP decrement (ΔMUCP) was found to be similar between the two ($P = 0.957$).

Various factors were evaluated to assess for risks predictive of surgical failure [Table 5]. Deduction of the multiple logistic regression analyses suggested two important predictors of surgical failure of a sling procedure, namely worse preoperative PT and use of MiniArc sling (OR = 5.747, $P < 0.05$).

Discussion

The study evaluated 130 women allotted into two SIMS groups (MiniArc and Solyx) with homogeneous preoperative demographics and clinical characteristics, showing high objective cure rates of 91.1% and 100%, and subjective cure rates of 93.7 and 90.2% at 3 months after surgery, respectively. The aforementioned success rates are compatible with previously published studies in the literature.[16] Two years' follow-up of the MiniArc system indicated that 82%–93% of subjects were continent.[17] The longest follow-up of 5 years after MiniArc sling insertion was reported by Lo *et al*.,[18] which demonstrated an objective and subjective cure rate of 84.7% and 80%, respectively. Data for Solyx SIS is very limited, but high subjective and objective cure rates were documented (85.5%, 90.3%, respectively with a mean follow-up of 21.4 ± 11.8 months in 113 females by Lo *et al*.;[19] 93%, 91%, respectively, with a mean follow-up of 43 months in 69 females by Serels and Douso[20]). Our objective cure rates are slightly higher than those observed in other studies, which may be due to the more versatile definition of objective cure applied in this study: fulfilling either a negative ST or PT weight <2 g, while other studies have required the presence of both conditions and/or dry PT.[5,21]

Described by Novara *et al*., MUS was merited superiority to colposuspension in a meta-analysis of 11 randomized controlled trials for the treatment of female SUI.[22] However, MUS-associated incommodious complications should not be overlooked. The complication rates ranged from 4.3% to 75.1% for retropubic and 10.5% to 31.3%

Table 3: Comparison of the objective and subjective outcomes at preoperation, 3- and 12- months postoperation

Objective outcomes	MiniArc (n=79)			Solyx (n=51)			MiniArc versus Solyx	
	Preoperative	Postoperative (3 months)	Pa (before vs. after)	Preoperative	Postoperative (3 months)	Pa (before vs. after)	Pb (postoperative 3 months)	Pb (postoperative 12 months)
1 h PT (g)	18.5±16.7	0.7±2.3	<0.001*	20.9±22.7	0.1±0.3	<0.001	0.013*	-
Negative ST, n (%)	5 (6.3)	64 (81.0)	<0.001*	4 (7.8)	47 (92.2)	<0.001	0.079	-
Subjective outcomes	**Preoperative**	**Postoperative (3 months)**	**Postoperative (12 months)**	**Preoperative**	**Postoperative (3 months)**	**Postoperative (12 months)**	**Pb (postoperative 3 months)**	**Pb (postoperative 12 months)**
UDI-6 Q3: No, n (%)	2 (2.5)	74 (93.7)	71 (89.9)	3 (5.9)	46 (90.2)	41 (80.4)	0.513	0.126
IIQ-7	73.3±29.2	4.1±13.9	4.2±10.1	90.9±13.2	4.3±10.1	4.7±11.0	0.931	0.811
UDI-6	41.7±20.6	3.0±5.8	2.9±6.0	39.6±11.0	3.5±6.1	5.0±7.1	0.665	0.081
PISQ	35.1±6.1	38.7±3.7	38.8±2.4	37.3±3.5	39.5±1.4	37.6±8.2	0.404	0.426
	MiniArc (n=79)			Solyx (n=51)			MiniArc versus Solyx	
	Preoperative	Postoperative (3 months)	Postoperative (12 months)	Preoperative	Postoperative (3 months)	Postoperative 12 months)	P (postoperative 3 months)	P (postoperative 12 months)
1 h PT<2 g, n (%)	11 (13.9)	72 (91.1)	-	4 (7.8)	51 (100)	-	0.042*	
Objective cure (PT<2 g or ST<0), n (%)	11 (13.9)	72 (91.1)	-	4 (7.8)	51 (100)	-	0.042*	
UDI-6 improvement score, mean±SD, (improvement rate)	-	3.2±1.2 (100)	3.2±1.2 (100)	-	2.6±0.9 (100)	2.6±0.9 (100)	0.003*	0.002*
IIQ-7 improvement score, mean±SD, (improvement rate)	-	6.2±1.7 (94.9)	6.3±1.6 (96.2)	-	7.0±0.1 (100)	7.0±0.1 (100)	<0.001* (0.154)	<0.001* (0.279)
PISQ improvement score, mean±SD, (improvement rate)	-	1.0±2.5 (36.8)	1.7±2.6 (48.5)	-	1.0±1.6 (40.0)	0.9±1.5 (31.8)	0.952 (1.000)	0.138 (0.220)

*Statistically significant P (P<0.05), [a]Paired t-test or McNemar test when applicable, [b]Student's t-test or Chi-square test when applicable, Data are presented as n (%) or mean±SD. P by Chi-square test, Fisher's exact test, or Student's t-test when appropriate. Objective cure rate: negative cough ST or PT<2 g. UDI, IIQ, PISQ improvement score (%): Percentage of patients obtaining improvement in symptom scores following the operation. PT: Pad test, ST: Stress test, SD: Standard deviation, UDI-6: Urogenital distress inventory, IIQ- 7: Incontinence impact questionnaire, PISQ: Prolapse incontinence sexual questionnaire, Q3: UDI-6 question number 3: "Do you experience urine leakage related to physical activity, coughing, or sneezing?", PISQ sexual questionnaire-SF: Short form limited to five questions, only for patients with sexual activity

Table 4: Comparison of the changes in urodynamic parameters: Pre- and post-operation

	MiniArc (n=79)			Solyx (n=51)			MiniArc versus solyx		SIMS total (n=130)		
	Preoperative	Postoperative (3 months)	P^a	Preoperative	Postoperative (3 months)	P^a	Pb (preoperative)	Pb (postoperative 3 months)	Preoperative	Postoperative (3 months)	P^a
MAX (ml/s)	20.4±8.2	18.7±7.4	0.072	18.4±6.2	19.4±7.7	0.353	0.127	0.564	19.6±7.5	18.9±7.5	0.371
ΔMAX (ml/s)	-	−1.8±8.8	-	-	1.1±8.1	-	-	0.064	-	−0.7±8.7	-
AVG (ml/s)	10.3±4.7	8.8±3.9	0.016*	9.5±5.6	8.9±3.7	0.393	0.383	0.936	10.0±5.0	8.8±3.8	0.015*
ΔAVG (ml/s)	-	−1.5±5.5	-	-	−0.7±5.5	-	-	0.390	-	−1.2±5.5	-
VVOL (ml)	301.9±152.1	309.7±132.8	0.701	279.8±129.0	297.7±147.3	0.410	0.392	0.631	293.2±14.4	305.0±138.2	0.431
ΔVVOL (ml)	-	7.8±180.5	-	-	18.0±154.4	-	-	0.742	-	11.8±170.2	-
PVR (ml)	42.6±64.6	33.9±43.7	0.274	41.6±50.7	40.8±58.5	0.944	0.925	0.439	42.1±59.3	36.6±49.9	0.378
ΔPVR (ml)	-	−8.7±70.4	-	-	−0.8±75.0	-	-	0.540	-	−5.6±72.0	-
MUCP (cmH2O)	67.6±28.9	56.0±23.2	0.001*	55.6±28.2	44.1±16.8	0.010*	0.021*	0.003*	62.9±29.2	51.4±21.7	<0.001*
ΔMUCP (cmH2O)	-	−11.9±29.3	-	-	−11.6±29.0	-	-	0.957	-	−11.8±29.1	-

*Statistically significant P (P<0.05), ΔInterval change. [a]Paired t-test, [b]Student's t-test. Data are presented as mean±SD. SD: Standard deviation, MAX: Maximal flow rate; AVG: Average flow rate; VVOL: Total voiding volume; PVR: Postvoid residual volume; MUCP: Maximal urethral closure pressure, SIMS: Single-incision mini-slings

for transobturator mid-urethral slings, including bladder perforation, hemorrhage, bowel injury, vaginal extrusion, *de novo* urgency, and voiding dysfunction.[23] Hence, SIS were introduced with multiple advantages to avoid blind needle insertion through the retropubic space or transobturator foramen. At the same time, they serve as the same suburethral "hammock" with less invasive technique, shorter trajectory, and a self-fixing tip feature. By simple elimination of external incisions and mesh implant lateral to the obturator, less anesthesia and operative time are required, allowing patients a quicker return to normal activities with less postoperative pain and higher satisfaction. Evaluation of recent literature shows equal cure rates, and fewer complications with the use of mini-slings compared to standard MUS.[24,25] Comparisons between the subtypes of SIMS are still sparse.

Urinary incontinence surgery with a mini-sling system is not free of complications. Alvarez-Bandrés *et al*. found a complication rate of 17% for MiniArc, although most were mild and could be successfully treated conservatively.[26] Adverse events were uncommon in the two studied groups, and none of the patients experienced urinary retention after the operation. In the past studies, *de novo* urgency showed a wide variation of 0%–36% incidence; over 30% was reported by Gauruder-Burmester and Popken,[25] while only 6.45% was described by Alvarez-Bandrés *et al*.[26] In this study, 9 patients (17.6%) from the Solyx group experienced *de novo* urgency at 1-year, significantly more than the MiniArc group (5 patients, 6.3%), P = 0.010, the exact cause is uncertain. Possible mechanisms contributing to this phenomenon could be traced to the intrinsic design of the Solyx slings (i.e. Detanged edges, wide tape width, thin anchors design, micro-adjustability), and individual voiding habits. These factors predispose the Solyx tape risks to be displaced away from the mid-urethra position which promotes *de novo* urgency.

Another possible advantage of a minimally invasive approach includes the reduced risk of postoperative suprapubic pain due to transobturator passage. Imamura *et al*. reported lower rate of suprapubic pain in patients following a transobturator sling procedure (8/687 [1.2%] vs. 27/681 [4.0%], 0.37 [0.17–0.84]) in a meta-analysis of randomized controlled trials.[27] Owing to the shorter insertion trajectory with no external incisions, VAS pain scores of both SIS groups were significantly lower than those for the TVT-O on the day following surgery.

Postoperative urodynamic testing has denoted a downward shift in both maximal (MAX) and average urine flow rates (AVG) in prior study by the author.[5] Some investigators have also reported decreased urine flow rates, elevated residual urine volume, and detrusor pressure at the maximum flow rate.[28] To that extent, the study attested a

Table 5: Multiple logistic regression analysis of surgical failure (pad test≥2 g or stress test>0)

Predictors	Coefficient	SE	OR	95% CI	*P*
Age	0.011	0.036	1.011	0.943–1.085	0.754
Parity	−0.189	0.291	0.828	0.468–1.464	0.516
BMI	0.127	0.085	1.135	0.962–1.339	0.134
Prior hysterectomy (yes vs. no)	−0.279	0.759	0.757	0.171–3.347	0.713
Preoperative PT	0.043	0.013	1.044	1.018–1.071	0.001*
Preoperative MUCP (≤40 vs. > 40)	0.869	0.635	2.384	0.686–8.279	0.172
Sling type (Solyx vs. MiniArc)	−1.746	0.748	0.174	0.040–0.756	0.020*
Blood loss during operation	−0.001	0.003	0.999	0.992–1.006	0.745

*Statistically significant P (*P*<0.05). BMI: Body mass index, MUCP: Maximal urethral closure pressure, SE: Standard error, OR: Odds ratio, CI: Confidence interval, PT: Pad test

significant decrease of AVG in the MiniArc but not Solyx users during the follow-up period. Since MiniArc system offers some degree of adjustability after deposition of the carrier, significant tissue irritation could occur if extensive adjustments were made, which could then lead to higher degree of tissue fibrosis underneath the urethra with larger decrement of AVG after the procedure. Despite the change, no significant voiding dysfunction was observed in either group. The urodynamic changes observed in the study may help to delineate the physiologic remodeling of suburethral and surrounding infrastructure following either sling surgery.

Although minimally invasive in nature and less tissue mingled in the process, the insertion of the mini-sling requires tension and placement juxtaposed to the suburethra, which could compromise the overall integrity of the urethral tissue and vasculature, leading to the expected reduction of MUCP in both groups ($P < 0.05$). Given the lower baseline MUCP found among the Solyx subjects, the interval change of MUCP (ΔMUCP) was assessed at 3 months postsling surgery. The result shows that there was no difference in the degree of drop in MUCP between MiniArc and Solyx groups ($P = 0.957$), while similar proportions of patients in each group preserved continence at follow-up. These findings suggest that the Solyx SIS is equally effective as the MiniArc without compromising urethral continence function, regardless of preliminary urethral condition.

Though high success rates were reported, the effect of SIS slings does not withstand permanently; stepladder decline of sling efficacy was observed through time, with various predisposed factors including age, hormonal status, and obesity (BMI >25). In a multivariate analysis study,[29] a few independent predictors for MUS failure were identified: BMI >25 (OR = 2.9), mixed incontinence (OR = 2.4), previous continence surgery (OR = 2.2), intrinsic sphincter deficiency (OR = 1.9), and diabetes mellitus (OR = 1.8). Lo *et al*. further revealed that prior prolapse surgery, neurogenic disease, constipation, and MUCP <40 cmH_2O, are risk factors that negatively influence SIS outcomes and may lead to failure of the procedure.[30] However, the current study showed that low MUCP (<40 cmH_2O) yielded negligible impact on the outcome of the sling surgery (OR = 2.384, $P = 0.172$). Further, this study identified risk factors for surgical failure not previously reported in literature, namely the preoperative PT and the use of different subtypes of mini-slings (exemplified with MiniArc and Solyx slings). Our preliminary data suggested that increased severity of preoperative PT (OR = 1.044) and implantation of the MiniArc sling rather than the Solyx tape (OR = 5.747) could result in increased failure rate.

This study presents several strengths and limitations. To the best of our knowledge, the study was the first to make direct comparison between two SIS systems (i.e. MiniArc and Solyx) in terms of clinical outcomes and urodynamic changes, noting that SIS subtypes may be predictive of surgical failure. The study may have limited clinical implications, as it is retrospective in nature with possible biases arising from relatively shorter follow-up period and absence of double-blinded, randomized study design.

Conclusions

The MiniArc slings officially withdrew from the market in July 2016, despite its excellence on efficacy and surgical outcomes reported in multiple long-term studies. Based on the objective and subjective measures observed in this 1-year study, both SIS surgical techniques appear to be equally effective and safe for the treatment of SUI. The use of the Solyx SIS shows a greater improvement in objective outcomes and comparable subjective outcomes, and more occurrences of postsurgical *de novo* urgency relative to the MiniArc slings. Our study also suggested that preoperative PT and sling-type could be predictive of surgical outcomes; specifically, better preoperative PT and the use of the Solyx SIS instead of the MiniArc device were associated with decreased risk for surgical failure. Therefore, this study demonstrated promising results for the use of the Solyx SIS as the main surgical treatment for female patients with SUI and should be considered as an alternative to the MiniArc system. However, multi-centered prospective randomized controlled

trials with a long follow-up and evaluation of quality-of-life and of the urodynamic changes are essential to validate the findings of the study and determine its true efficacy.

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Conflicts of interest

There are no conflicts of interest.

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