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Research Paper

Medium-term clinical efficacy and safety of single incision and modified trans-obturator mid-urethral slings for female stress urinary incontinence

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ABSTRACT

Aims: To evaluate the medium term efficacy and safety of Altis and Solyx single incision slings (SIS) compared with tension-free vaginal tape (TVT) Abbrevo trans-obturator sling. We hypothesize that both SIS show little difference in efficacy and safety and perform similarly to TVT Abbrevo.
Methods: We conducted an ambispective comparative cohort study of women with stress urinary incontinence who received a SIS in comparison to matched TVT Abbrevo subjects from a concurrent randomized controlled trial (RCT). Subjects were identified retrospectively, and prospectively invited for examination and questionnaires>12 months post-operatively. Exclusions included intrinsic sphincter deficiency, previous sling surgery, and others. Primary outcome was subjective cure [negative response to International Consultation Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF) question 6, leakage during coughing/activity]. Secondary outcomes include objective cure (negative cough stress test), functional outcomes, and adverse events.
Results: Between 2012 and 2018, a total of 113 women received one of two SIS surgeries; Solyx (n = 50) followed by the Altis (n = 63); 104 were available for final efficacy analysis. Mean follow-up was 21.7 (Altis), 46.0 (Solyx), and 29.0 (Abbrevo) months. Baseline characteristics were comparable between the groups. There was no significant differences in the subjective or objective cure rates between the groups, and no differences in functional outcomes such as patient global impression of improvement, and post-operative ICIQ-UI SF score. There was a low rate of mesh related complications and no differences seen between the groups.
Conclusions: Despite being an underpowered study, Altis and Solyx SIS have favourable efficacy and safety profiles which are comparable to an established trans-obturator mid-urethral slings (MUS).

1. Brief summary

Single incision slings, Altis and Solyx, appear comparable to trans-obturator sling over medium-term follow-up, with a low rate of complications.

2. Introduction

Single incision slings (SIS) or "mini-slings" are the most recent generation of mid-urethral slings (MUS) used to treat female stress urinary incontinence (SUI). In keeping with other synthetic MUS, SIS are made of type 1 non-absorbable (polypropylene) mesh, but are shorter than conventional slings. They are placed through a single vaginal incision at the level of the mid-urethra and fixed laterally with anchors through the

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obturator membrane without exiting the groin. SIS were developed in an attempt to maintain the efficacy of retropubic and trans-obturator MUS, with reduced risk of visceral injury or bleeding by avoiding passage through the retropubic space, and potentially a lower risk of groin pain through limited passage through the groin musculature.

This study has been primarily undertaken to compare the efficacy (primary outcome) and functional and safety (secondary outcomes) of two types of SIS, Altis and Solyx, with tension-free vaginal tape (TVT) Abbrevo (a modified trans-obturator sling). These slings have been used in clinical practice in Australia and around the world, and additional device specific data would be beneficial to support their ongoing use. We hypothesize that both single incision slings show little difference in efficacy and safety and perform similarly to TVT Abbrevo.

Whilst SIS are currently available in other jurisdictions internationally, on January 2018, Australia's regulatory body, the Therapeutic Goods Administration (TGA), removed SIS from its Australian Register of Therapeutic Goods (ARTG) – the first and, to date, only occasion of its restriction worldwide.[1] The TGA stated that this decision was due to a paucity of comparative device-specific efficacy and safety data on the available SIS. Contextual events included the earlier withdrawal of TVT Secur™ (Gynecare, Somerville, MA) due to decreased efficacy and the collapse of American Medical Systems (AMS) and Astora leading to market withdrawal of the MiniArc™ which had the most available single incision sling data at that time. At present, three-year follow-up comparative studies have been mandated by the Federal Drug Administration and completed in some cases.[2] This analysis will add to the body of comparative data available for existing SIS.

3. Materials and methods

3.1. Study design and population

We conducted an ambispective comparative cohort study with retrospective recruitment and prospective follow-up of all women who received an Altis or Solyx single incision sling for symptomatic SUI at a urogynecological centre in Melbourne, Australia between 2012 and 2018. In general, the Altis cohort was proceeded by the Solyx cohort due to market release and availability, with some overlap. These two SIS cohorts were then compared to a historical cohort of TVT Abbrevo (Gynecare, Somerville NJ) from a concurrent randomised trial in our unit,[3] chosen due to overlapping time frames and likely similar demographics. All women had failed conservative management and, following office and urodynamic assessment and counselling for surgical management of SUI, had received either SIS at the surgeons' discretion. At that time, this was offered as standard clinical practice in women who fulfilled the inclusion criteria of age 35 years or greater, completed their family with symptomatic SUI demonstrated on office evaluation and, either urodynamic study and/or positive pad weigh test (>4.4 g/24 h).[4] Patients who undertook concomitant prolapse surgery were included.

Exclusion criteria were: previous sling, refractory or untreated detrusor overactivity, intrinsic sphincter deficiency (defined as abdominal leak point pressure (ALPP) < 60 cmH_20 and/or maximal urethral closure pressure (MUCP) < 20 cmH_20), significant voiding dysfunction (post-void residual volume >150 ml), pelvic radiation, past or present genitourinary fistula or urethral diverticulum repair. The TVT Abbrevo study had the same inclusion and exclusion criteria.[3]

3.2. Surgical technique

All SIS surgery was performed by experienced surgeons (urogynecologist or senior urogynecology fellow) who were proficient in inserting both surgical devices. Ninety percent of SIS were performed by the senior author. The centre had a long experience of another previously available single incision sling with similar insertion technique.[3,5]

The Solyx (Boston Scientific Corporation, Marlborough MA) and Altis (Coloplast Corporation, Minneapolis MN) SIS comprise a 9 cm and 7.75 cm length sling respectively, composed of polypropylene knitted type 1 mesh with polypropylene anchors. A 1.5 cm incision is made at the level of the mid-urethra followed by dissection bilaterally to the inferior pubic ramus at a 45° angle from the midline. The deployment mechanism is inserted into the dissection plane and released when the midline of the mesh is reached, and repeated on the opposite side. Tension is set without excess tension so that no space exists between the mesh and midurethral tissue. Altis® (Coloplast) SIS also contains a dynamic tensioning suture, allowing the surgeon to tension the sling with traction of a tensioning suture loop across the midline after bilateral anchoring. The vaginal incision is closed and a cystourethroscopy is performed.

3.3. Outcome measures

Primary outcome was subjective cure defined as a negative response to leakage with cough/sneeze and exercise/physical activity [International Consultation on Incontinence – Urinary Incontinence Short Form (ICIQ-UI SF) question 6, parts c and e].[6]

Secondary outcomes included objective cure defined as a negative cough stress test (CST) with a comfortably full bladder in the standing position[5]; Patient Global Impression of Improvement (PGI-I) score[7] and proportion of those "much better" or "very much better"; ICIQ-UI SF[6] total score and proportion of those with a post-operative ICIQ-UI SF cut off score <6/21 which has been validated with a successful outcome[8]; and the proportion of patients using overactive bladder medications post-operatively. Serious adverse events such as repeat surgery for mesh exposure, sling division/loosening, complete removal, and repeat continence surgery, duration of post-operative groin, vaginal, or pelvic pain was obtained through review of patient files. Other secondary outcomes included post-operative uroflowmetry measures (maximum flow rate, post-void residual volume) and sling to symphysis pubis measurements at rest and valsalva via translabial ultrasound.

Invitation to take part in the study was initiated by a letter mail-out followed up with a phone call by a research nurse or urogynaecology fellow, blinded to all other data. Study investigators were blinded to treatment groups. Participation was voluntary and did not impact on medical care. Those subjects who were unable to physically attend for an appointment were asked to complete the questionnaires. Clinical examination included a standing CST, standardised POP-Q examination; vaginal and groin examination for mesh exposure or tenderness, uroflowmetry, and translabial 3D ultrasound.[9,10]

3.4. Data handling and analysis

Sample size of each arm was fixed during the study due to de-listing of SIS by the TGA during the study. We estimated that to achieve power each arm would require >250 cases which was not feasible. Statistical analysis was completed using SPSS version 21. The statistical significance was set at $P < 0.05$.

Differences in categorical variables between groups were tested with Chi-squared test or Fisher's exact test. Differences in continuous variables were tested with one-way analysis of variance (ANOVA) for outcomes showing normal and Kruskal-Wallis test for outcomes showing non-normal distribution. Bonferroni correction was used for pairwise comparison. Within group comparison for continuous variables (preoperative vs. postoperative) was performed with paired sample T-test. We calculated Pearson's correlation between symphysis to sling distance at Valsalva and post-operative maximum flow rate. Odds ratios for cure rates were estimated with binary logistic regression. Since the follow-up time differed between the groups, we also performed a sensitivity analysis adjusting with the follow-up time.

4. Results

A total of 113 women received a SIS between the years 2012–2018 (63 Altis and 50 Solyx). 9 were excluded from the efficacy analysis (2

diagnosed with intrinsic sphincter deficiency, 2 lost to follow-up, 5 declined to take part in the study) leaving 104 for final analysis, including 60 Altis and 44 Solyx. Of these 104, 92.3% (96/104) filled questionnaires for primary outcome (subjective cure), 85.6% (89/104) presented for cough-stress test (objective cure) and examination (Fig. 1).

Table 1 demonstrates the baseline characteristics for the entire cohort including Altis, Solyx, and TVT Abbrevo groups. Baseline characteristics were balanced between the groups apart from small mean difference in age of 3 years and subsequent menopausal status, and parity by 1. Greater than fifty percent of the cohort had concomitant prolapse surgery.

The mean follow-up time for each sling was: Altis 21.7 months (range 12–31), Solyx 46.0 months (range 14–71), and TVT Abbrevo 29.0 (18–60) months. The subjective and objective cure rates showed no significant differences between the groups, when comparing those that also received concomitant prolapse surgery or sling only subjects (Table 2). Functional outcomes including PGI-I, ICIQ-UI SF total score and those with an ICIQ-UI SF score of <6/21,[8] and those using bladder relaxants post-operatively did not differ between groups (Table 3). In sensitivity analysis, adjusting for the duration of follow-up, the difference remained statistically insignificant for each outcome. The results do not show any significant difference when assuming loss to follow-up as failures.

Mesh related adverse events (Table 4) were low in all groups with no significant differences seen in minor mesh exposure, minor mesh excision, sling removal, sling loosening, or repeat sling for failure. There was one case of total sling removal at one week post-operation in the Altis group for severe groin pain and a retropubic sling was placed at that time. One Altis sling was divided at 5 months post-operatively for chronic low grade voiding dysfunction following episodic clean intermittent self-catheterisation. A total of 7 repeat slings were performed (Altis n = 2, Solyx n = 3, TVT Abbrevo n = 2, p = 0.307); these were 4 retropubic MUS within 6 months and 1 at 6 years in the SIS group, and 2 repeat MUS at 5 years in the Abbrevo group. Five slings were loosened in the first post-operative week for voiding dysfunction (Altis = 1, Solyx = 2, TVT Abbrevo = 2, p = 0.605), after which voiding improved.

Early groin or vaginal pain lasting up to 3 months was reported as higher in the Altis group. In the SIS group all pain was reported as

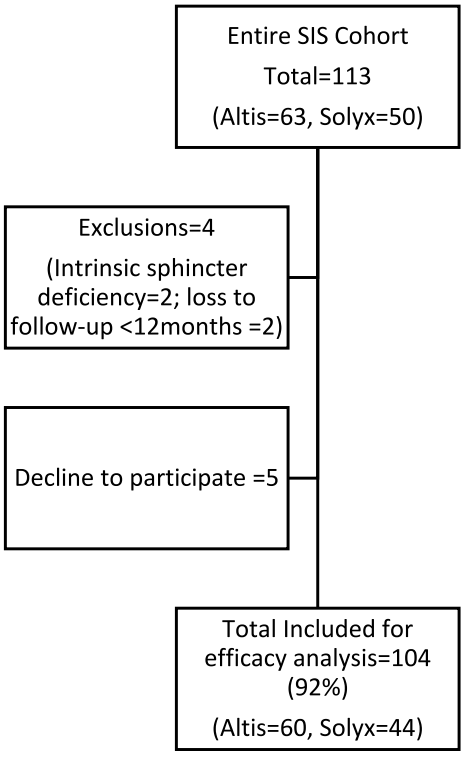

Fig. 1. Study flowchart.

Table 1
Baseline characteristics, Altis vs Solyx vs TVT Abbrevo.

Characteristics	Altis (n = 63)	Solyx (n = 50)	Abbrevo (n = 119)	*p*-value for all	Data available Altis/ Solyx/ Abbrevo
Demographic					
Age, y, mean ± SD	55.3 ± 11.6	52.2 ± 11.7	50.8 ± 9.9	0.032	63/50/118
Parity total [median (IQR)][a]	2 (2,3)	2 (2,3)	3 (2,3)	0.032	61/49/99
Parity vaginal [median (IQR)]	2 (2,3)	2 (1,3)	3 (2,3)	0.004	61/49/99
BMI, mean ± SD	26.2 ± 5.3	26.0 ± 4.1	26.1 ± 5.1	0.98	56/44/95
Post menopausal status, n (%)	35 (55.6)	21 (45.7)	28 (28.0)	0.001	63/46/100
Previous Hysterectomy, n (%)	9 (14.3)	5 (10.9)	15 (16.7)	0.661	63/46/90
Previous POP surgery, n (%)	3 (4.8)	4 (8.7)	13 (12.5)	0.247	63/46/104
Previous SUI surgery, n (%) (Burch colposuspension n = 5)	5 (7.9)	0 (0)	3 (2.9)	0.087	63/46/103
Total PMHx, n (%)[b]	17 (27.0)	9 (19.6)	16 (14.8)	0.151	63/46/108
Baseline Functional Outcomes					
PGI-S [median (IQR)][a]	3 (3,4)	3 (3,4)	3 (2,3)	<0.001	56/42/105
Antimuscarinic use, n (%)	5 (8.3)	7 (14.6)	7 (7.4)	0.357	60/48/95
Urodynamic findings					
Detrusor overactivity, n (%)	7 (11.5)	2 (4.1)	7 (6.6)	0.407	61/49/106
MUCP (cm H_20), mean ± SD	45.7 ± 18.0	43.5 ± 19.4	42.2 ± 16.3	0.492	55/47/98
ALPP (cm H_20), mean ± SD	121.1 ± 31.9	119.1 ± 34.4	115.3 ± 46.4	0.697	48/46/91
Maximum flow rate (ml/sec), mean ± SD	31.9 ± 14.2	30.7 ± 12.5	26.4 ± 10.8	0.014	61/49/101
Post void residual volume (ml), mean ± SD	22.4 ± 25.3	24.4 ± 26.3	27.8 ± 28.2	0.448	61/49/104
POP-Q staging [median (IQR)][a]					
Ba	−1 (−2, 0)	−1 (−2, 0)	−1 (−2, 0)	0.132	51/47/101
Bp	0 (−2, 0)	−2 (−3, 0)	−1 (−2, 0)	0.056	51/48/98
C	−5 (−6, −4)	−6 (−7, −5)	−6 (−7, −4.75)	0.043	52/46/99
Prolapse surgery					
Concomitant POP, n (%)	34 (54.0)	26 (55.3)	61 (51.3)	0.875	63/47/119
VH ± A/P or AP, n (%)	27 (42.9)	23 (50.0)	49 (41.2)	0.588	63/46/119
Anterior/apical mesh, n (%) (Uphold® TVM or ASC)	2 (3.2)	1 (2.2)	2 (1.7)	0.838	63/46/119
Posterior Repair, n (%) (no posterior mesh)	5 (7.9)	2 (4.3)	10 (8.4)	0.75	63/46/119

Maximum flow rate: post void residual assessment performed at uroflowmetry prior to consent for continence surgery.
PGI-S:patient global impression of severity; MUCP: maximum urethral closure pressure; ALPP: abdominal leak point pressure; VH ± A/P or AP: vaginal hysterectomy, vault suspension, anterior ± posterior repair; TVM: transvaginal mesh; ASC: abdominal sacrocolpopexy; POP: Pelvic Organ Prolapse; PMHx: Past Medical History; SUI: stress urinary incontinence, n: number of cases.
[a] Median (interquartile range Q1,Q3).
[b] Medical history of diabetes milletus, cardiovascular, respiratory, neurological, connective tissue disorders.

Table 2
Subjective and objective cure rates of Altis vs Solyx vs TVT Abbrevo.

Treatment	Cure	OR[a]	95% CI	*p*-value	Adjusted OR[b]	95% CI	*p*-value	Data available
Cure rate sling ± concomitant surgery								
Subjective, n (%)								
Altis n = 60	40 (71.4)	1		0.866	1		0.595	56
Solyx n = 44	29 (72.5)	1.06	0.43–2.61		1.89	0.50–7.11		40
Abbrevo n = 93	67 (75.3)	1.22	0.57–2.56		1.42	0.64–3.18		89
Objective, n (%)								
Altis n = 60	48 (94.1)	1		0.304	1		0.554	51
Solyx n = 44	34 (89.5)	0.53	0.11–2.53		0.89	0.08–9.46		38
Abbrevo n = 93	86 (96.6)	1.79	0.35–9.23		2.08	0.37–11.83		89
Cure rate sling only								
Subjective, n (%)								
Altis n = 26	20 (83.3)	1		0.385	1		0.371	24
Solyx n = 17	14 (87.5)	1.4	0.23–8.72		1.82	0.14–23.12		16
Abbrevo n = 46	32 (72.7)	0.53	0.15–1.88		0.58	0.15–2.28		44
Objective, n (%)								
Altis n = 26	16 (88.9)	1		0.123	1		0.193	18
Solyx n = 17	11 (78.6)	0.46	0.07–3.21		0.36	0.01–17.79		14
Abbrevo n = 46	43 (97.7)	5.38	0.46–63.43		4.98	0.34–73.82		44

Subjective cure defined as a negative answer on questions 3 and 5 of the International Consultation on Incontinence Questionnaire – Urinary Incontinence Short Form. Objective cure defined as negative cough stress test.
[a] Logistic regression, Altis as the reference category
[b] Logistic regression, adjusted for follow-up time.

resolved before 3 months except for 3 Altis patients who reported resolution at 3, 6, and 12 months respectively with simple analgesia and physiotherapy. Of the TVT Abbrevo group, all but one case reported resolution of pain; this patient had no mesh tenderness, has received physiotherapy and injections of local anaesthesia and Botulinum toxin to the pelvic floor muscles and continues to have groin and vaginal pain at 5 years, is continent and to date, chosen not to have the sling removed.

The maximum flow rate (MFR), post void residual (PVR), and symphysis to sling distance for Altis, Solyx, and TVT Abbrevo are shown in Table 5. Only the Altis demonstrated change in maximum flow rate (34.9 ml/s vs 26.6 ml/s, p = 0.005) and PVR (25.6 ml vs 43.6 ml, p = 0.013). Despite these values reaching statistical significance, the values remain within normal limits and are unlikely to be relevant clinically. There was no correlation between symphysis to sling distance at valsalva and postoperative maximum flow rate for either of the sling groups.

5. Discussion

Altis and Solyx SIS appear to have comparable efficacy and safety over a mean follow-up period of 32 months. These findings are consistent with the literature. Prospective single-arm studies on Altis SIS over 12–24 months follow-up found similar subjective and objective cure rates ranging from 80% to 90%.[11–15] A 522 post-market prospective multi-centre study of Solyx compared with a transobturator MUS (Obtryx II) demonstrated non-inferiority over 36 months follow-up with comparable safety and efficacy (90.4% vs 88.9%, Solyx vs Obtryx II). Composite success defined as negative cough stress test and improvement on PGI-I),[2] and using this same definition of composite success, our cohort demonstrate slightly lower success rates with still no significant difference between the groups (Altis 84% vs Solyx 78.9%, p = 0.586). Longer-term retrospective studies on Solyx of 69 subjects with a mean follow-up of 43 months demonstrated 93% subjectively dry by questionnaire and satisfied with their outcome, with no serious adverse events.[16]

Table 3
Functional outcomes of Altis vs Solyx vs TVT Abbrevo.

Functional Outcome (entire cohort)	Altis (n = 60)	Solyx (n = 44)	Abbrevo (n = 93)	*p*-value	Data available Altis/Solyx/ Abbrevo (n)
PGI-I [median (IQR)][a]	1 (1,2)	2 (1,3)	1 (1,2)	0.233	56/41/88
Score = 1 or 2; "Very much" or "much better" n (%)	48 (85.7)	29 (70.7)	77 (87.5)	0.05	56/41/88
Postop ICIQ UI-SF total score [median (IQR)][a]	3 (0, 5.5)	4 (0.5, 10.5)	4 (0, 6)	0.395	56/40/89
Score <6 n (%)	42 (75)	26 (65)	65 (73.0)	0.531	56/40/89
OAB Medications n (%)	7 (12.5)	4 (13.8)	3 (4.0)	0.133	56/29/75

PGI-I:Patient Global Impression of Improvement; ICIQ UI-SF: International Consultation on Incontinence Questionnaire - Short Form; OAB: Overactive Bladder.
‡PGI-I score, 1 = "very much better".
[a] Median (interquartile range Q1,Q3).

Table 4
Mesh related complications of Altis vs Solyx vs TVT Abbrevo.

Complications	Altis	Solyx	Abbrevo	*p*-value	Data available A/S/Abbrevo (n)
Entire cohort[a]					
Mesh exposure, n (%)	0 (0)	2 (4.3)	3 (2.6)	0.34	63/47/116
Minor mesh excision, n (%)	0 (0)	1 (2.1)	3 (2.6)	0.539	63/47/116
Sling removed entirely (1)/divided (2), n (%)	2 (3.2)	0 (0)	1 (0.9)	0.299	63/47/116
Sling loosened early, n (%)	1 (1.6)	2 (4.3)	2 (1.7)	0.605	63/47/116
Repeat sling, n (%) (within 6 m post-op n = 4, at 5–6 yrs n = 3)	2 (3.2)	3 (6.4)	2 (1.7)	0.307	63/47/116
Sling only[b]					
Mesh exposure, n (%)	0 (0)	0 (0)	2 (3.6)	0.696	29/19/55
Minor mesh excision, n (%)	0 (0)	0 (0)	2 (3.6)	0.696	29/19/55
Sling removed entirely (1)/divided (1), n (%)	2 (6.9)	0 (0)	0 (0)	0.11	29/19/55
Sling loosened early, n (%)	1 (3.4)	2 (10.5)	2 (3.6)	0.443	29/19/55
Repeat sling, n (%)	2 (6.9)	3 (15.8)	2 (3.6)	0.193	29/19/55

PGI-I:Patient Global Impression of Improvement; ICIQ UI-SF: International Consultation on Incontinence Questionnaire - Short Form; OAB: Overactive Bladder.
[a] Altis (n = 63), Solyx (n = 50), Abbrevo (n = 119).
[b] Altis (n = 29), Solyx (n = 21), Abbrevo (n = 58).

Table 5
Uroflowmetry and Ultrasound of Altis vs Solyx vs TVT Abbrevo.

	Altis (n = 60)	Solyx (n = 44)	Abbrevo (n = 93)	Intergroup comparison p-value	Data available Altis/Solyx/ Abbrevo(n)
Uroflow[a]					
MFR Preoperative, mean ± SD	34.9 ± 15.2	29.2 ± 11.0	30.0 ± 13.1	0.206	37/23/25
PVR Preoperative, mean ± SD	25.6 ± 25.2	26.5 ± 29.0	27.3 ± 28.8	0.912	37/23/24
MFR Postoperative, mean ± SD	26.6 ± 14.2	28.2 ± 12.2	30.2 ± 10.1	0.541	37/23/25
PVR Postoperative, mean ± SD	43.6 ± 37.4	39.4 ± 33.8	14.0 ± 16.2	0.002	37/23/24
MFR change, mean ± SD	−8.3 ± 16.7	−1.0 ± 12.3	0.27 ± 15.5	0.064	37/23/25
PVR change, mean ± SD	18.0 ± 41.9	12.8 ± 41.5	−13.3 ± 35.8	0.012	37/23/24
MFR change (intragroup preop vs postop)	0.005	0.701	0.931		37/23/25
PVR change (intragroup preop vs postop)	0.013	0.153	0.082		37/23/24
Symphisis-Sling distance					
Sling distance at valsalva, mean ± SD	13.8 ± 2.9	14.5 ± 2.9	13.8 ± 3.6	0.579	49/32/29
Sling distance at rest, mean ± SD	15.7 ± 4.5	16.3 ± 3.7	15.9 ± 4.5	0.843	49/32/29

(n): number of cases; MFR: maximum flow rate; PVR: post void residual; assessment performed at uroflowmetry prior to consent for continence surgery Sling distance (mm).
Pairwise comparison, p-values (Bonferroni method); PVR postoperative, p = 1.00 (Altis vs Solyx); p = 0.002 (Altis vs Abbrevo); p = 0.023 (Solyx vs Abbrevo), PVR change, p = 1.00 (Altis vs Solyx); p = 0.012 (Altis vs Abbrevo), p = 0.086 (Solyx vs Abbrevo).
[a] Uroflow:included all cases with both pre or postop uroflow data available for comparison, excluded patients with voided volume <150 ml.

Grouped as a whole and compared to retropubic or transobturator slings, SIS show variable results. This appears to depend on whether the grouped data includes studies of the first single-incision sling on the market, the TVT Secur™. The 2014 Cochrane review on SIS which included randomised studies of TVT Secur™ demonstrated inferior efficacy of SIS to retropubic and *trans*-obturator MUS.[17] Likewise, a systematic review from 2011 demonstrated inferiority of SIS compared with MUS for subjective and objective cure,[18] but similar efficacy once TVT Secur™ was removed from the analysis.[19] Likewise, much of the pooled early data on SIS efficacy and safety includes data on MiniArc™, which is no longer available. This highlights the importance of obtaining device specific data, as each SIS is variable in its design, and hence its efficacy and safety profile.

Our study demonstrated higher objective cure rates compared with subjective cure, a finding commonly seen in other studies.[20] This may be explained by our relatively stringent definition of cure, where a negative response was required to any leakage during cough, sneeze, and physical exertion. Many patients would consider success to be "much better" or "very much better" (using the terminology of PGI-I), which is why this is included in our results. The subjective cure rate using this latter definition increased to 85.7% in the Altis group (22 month follow-up), and reduced slightly to 70.7% in Solyx (46 month follow-up), with still no statistically significant difference between the groups.

There are several possible explanations for the somewhat higher short-term vaginal and groin pain rate found in the more recent Altis cohort. It is possible that this is an example of reporting bias with more thorough questioning and clinician and patient awareness of post-operative pain in the global and local mesh climate. It is possible that it is related to the sling, its insertion trocar or tensioning suture, however its significance is doubtful as in all cases there was resolution.

This cohort study has some benefits including a broad inclusion criteria and the inclusion of cases with concomitant prolapse surgery making it translatable into clinical practice. There remain several limitations that require highlighting. Our study had a retrospective design and was unpowered for its primary outcome, with incomplete data for uroflowmetry and ultrasound assessment. Seven (Altis = 3 vs Solyx = 4) patients were unable to be contacted or declined follow-up, which may represent selection bias where discontented patients or failures chose not to return for follow-up. Assuming all of these patients as failures, the results would not be significantly impacted. Furthermore, there was a longer follow-up period for the Solyx cohort which may have allowed greater time for failures to appear, however cure rates remained similar between the groups when adjusted for the difference in follow-up times.

Furthermore, it is uncertain whether the contextual climate in Australia following the TGA de-listing of SIS during the study had an impact upon patient reported symptoms. During the follow-up period, mesh controversies and subsequent vaginal and groin pain reports were publicised heavily in the Australian media including a Parliamentary Senate enquiry on transvaginal mesh. This context may have had the positive effect of increasing study participation and increased retrospective reporting of pain.

6. Conclusions

The results of our study demonstrate that both Altis and Solyx SIS have favourable efficacy and safety profiles which are comparable to an established trans-obturator MUS. This study is limited by being underpowered and further longer-term randomised or comparative cohort studies are required to confirm these findings. Further efficacy and registry data for uncommon adverse events will support the use of SIS in order to provide another option for the surgical treatment of stress incontinence in women. This data will not readily be available from Australia due to de-listing of SIS devices.

Conflict of interest

No conflict of interest.

Author contributions

JM: Protocol/project development, Data collection and management, data analysis, manuscript writing and editing, PKK: Data collection and management, data analysis, manuscript editing, CM:Data collection and management, manuscript editing, JKL: Protocol/project development, data analysis, manuscript editing, AR:Protocol/project development, data collection, data analysis, manuscript editing.

Declaration of interests

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: This study was not directly funded. Boston Scientific (partial funding) – this study included 17 Solyx patients that were part of a 522 study funded by Boston Scientific at our institution. Coloplast funded only the hospital ethics application submission milestone of a randomised controlled trial (RCT) comparing Altis with retropubic sling which had not yet commenced when Single-Incision Slings became de-listed by the Therapeutic Goods Administration (TGA).

Ethical considerations

Institutional ethics approval was obtained (#04-26-02-18). Informed consent was obtained from all subjects. This study conforms to the STROBE guidelines for observational studies.

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