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Original Article

Single incision anterior apical mesh and sacrospinous ligament fixation in pelvic prolapse surgery at 36 months follow-up

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ABSTRACT

Objective: To compare the clinical efficacy, recurrence, complications and quality of life changes 3 years after Elevate-A/single incision mesh surgery anterior apical (SIM A) and sacrospinous ligament fixation (SSF) in the management of pelvic organ prolapse (POP).

Materials and methods: A prospective cohort study, 139 women, underwent transvaginal surgery for anterior and/or apical POP > stage 2, 69 patients had SIM A and 70 patients had SSF. The objective cure was defined as POP ≤ stage 1 anterior, apical according to POP-Q. Subjective cure is patient's negative feedback to question 2 and 3 of pelvic organ prolapse distress inventory 6 (POPDI-6). Patient's satisfaction was reported using validated quality of life questionnaires. Multi-channel urodynamic study was used to report any voiding problems related to the prolapse surgery 6 months after surgery.

Results: 119 patients completed a minimum of 3 years follow-up. 89.8% is the overall prolapse correction success rate for SIM A and 73.3% for SSF group ($p = 0.020$), and 96.6% versus 73.4% at the anterior vaginal compartment respectively ($p \leq 0.001$). Statistically significant difference was noticed in apical compartment with 98.3% with SIM A and 85.0% with SSF ($p = 0.009$). The subjective success rate, 86.4% in the SIM A and 70.0% in the SSF arm ($p = 0.030$) was significantly noted. Only, Pelvic Organ Prolapse Distress Inventory-6 (POPDI-6) showed significant improvement. Operation time and intra-operative blood loss tend to be more with SIM A.

Conclusion: SIM A has better 3 years objective and subjective cure rate than SSF in the anterior and/or apical compartment prolapse.

Introduction

Approaches to the surgical management of pelvic organ prolapse (POP) have undergone several paradigm shifts over the last few decades [1]. Innovative technologies are being incorporated into treatment modalities, specifically in the arena of surgical devices. An ideal prolapse repair would be simple, effective, and durable procedure with less morbidity and short recovery time. Numerous surgical procedures have been described either vaginally or abdominally in the attempt to provide the best surgical repair for POP. One of the most common procedures performed for the correction of apical prolapse is the sacrospinous ligament fixation (SSF).

Although the efficacy of unilateral SSF in preventing and treating apical prolapse ranged between 78 and 96% [1], the recurrence of anterior prolapse after the surgery led to its popularity waning

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between surgeons especially with the development of graft used in pelvic reconstructive surgery. Lo et al. reported a favorable and sustainable anatomical and subjective outcomes result over 5 years in cases of advanced POP, comparing SSF with non-absorbable anterior vaginal mesh and anterior colporrhaphy [2].

Transvaginal mesh (TVM) augmented surgery for the treatment of POP has been introduced in an attempt to improve long-term durability of vaginal POP surgery. Regaining popularity currently is the mesh kit which includes apical support apart from the normal anterior and posterior compartment support. One such kit is the Elevate-A (Elevate® Anterior and Apical Prolapse Repair System, American Medical Systems, Minnetonka, MN, USA) (SIM A, single incision mesh-anterior apical) which is now used for anterior and apical prolapse repair.

Literature reviews on SSF and anterior apical prolapse repair are still lacking. Thus, our aim is to evaluate the objective and subjective success rates and safety issue regarding the use of SIM-A compare to SSF and to establish any superiority for one over the other at third year post-operatively.

Materials and methods

Institutional Review board approval was obtained for this prospective cohort study, (IRB#: 99-0037B), which was carried out between May 2010 and April 2012 in CGMH Taipei and Linkou. All patients who attended the urogynecology clinic during the study period with symptomatic anterior or apical prolapse >stage 2 according to the pelvic organ prolapse quantification system (POP-Q)/international continence society (ICS) [7] were enrolled. Patients from Taipei were offered SIM-A while patients from Linkou were offered SSF repair.

Women who had preoperative stress urinary incontinence (SUI), previous POP mesh-augmented surgery, previous anti-incontinence procedures and who were medically unfit for surgery were excluded. Preoperative SUI was diagnosed based on clinical symptoms, cough stress test and multichannel urodynamic evaluation (UDS); which were performed in semi-lithotomy position with a ring pessary for prolapse reduction. Urodynamic stress incontinence (USI) was defined as an involuntary urinary leakage with the increased in intraabdominal pressure in the absence of detrusor contraction during filling cystometry. Patients who had SUI only when prolapse has been repositioned were considered to have occult SUI. All women with overt or occult SUI were excluded in this study.

Preoperative baseline assessments included detailed clinical history and physical examination; including pelvic examination, cough stress test, baseline urine analysis, 1-h pad test, 72-hr micturition diary. Multichannel UDS with a ring pessary for prolapse reduction were done regardless of complaints of urine leakage in order to diagnose occult SUI. POP staging was recorded according to POP-Q system [3]. All patients were required to fill up questionnaires, i.e: Incontinence Impact Questionnaire-7 (IIQ-7) [4], Urogenital Distress Inventory 6 (UDI-6) [5], Pelvic Organ Prolapse Distress Inventory 6 (POPDI-6) [6], and Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire (PISQ-12) [7]. Validated Chinese versions were used [8]. All conditions were defined according to ICS standards [3].

Pre-operatively, all women were counseled regarding treatment options including the potential benefits and complications during the operation and post-operatively. Informed consent was secured prior to treatment.

Operative procedure

All surgical procedures were performed in the following order: vaginal hysterectomy, Elevate A: Elevate® Anterior and Apical Prolapse Repair System implantation or right-sided posterior approach SSF. Anterior and posterior colporrhaphy were performed if indicated.

For patients who developed USI after the operation and required surgical interventions, interval anti-incontinence surgery was performed using midurethral sling (MUS).

In brief, for SIM-A: after hydrodissection of the vesicovaginal space, a single full thickness vertical incision was made on the anterior vaginal wall. The paravesical fossa was dissected bilaterally from the level of the ischiopubic ramus to the ischial spine until both the sacrospinous ligaments (SSL) were identified. The vaginal apex was transfixed at the proximal end of the mesh and both the apical self-fixating strips were inserted into SSL bilaterally. The distal end of the mesh was transfixed to the urethrovesical junction while the distal self fixating tip was anchored to the obturator internus muscle. SIM-A mesh was trimmed intra-operatively approximately at the junction of the two distal arms which resulted in an implanted mesh measurement of 5.0 × 6.5 cm.

In the SSF group: the vaginal vault was attached to the SSL via a posterior approach using monofilament polypropylene number 1 (Prolene™, Ethicon, Nashville, TN, USA) following the unilateral right-sided procedure described by Miyazaki [9].

Intraoperative cystoscopy was performed for all patients to evaluate the integrity of the lower urinary tract. Prophylactic antibiotic intravenous Cefazolin 500 mg were given preoperatively and every 6 h for 24 h. Vaginal packing was done with gauze soaked with Povidone Iodine and was removed after 24 h. Foley's catheter was inserted during the operation and left in place for 24 h. Patients were encouraged to void freely following Foley's catheter removal and discharged home if residual urine (RU) was consistently <20% of the voided volume. Bladder was scanned (BVI 3000; Diagnostic Ultrasound Corp., Bothell, WA, USA) for post-void residuals every 4 h after catheter removal. Sterile, intermittent catheterization was performed when the post-void RU exceeded 150 ml and will stop only once the RU is <150 ml. Clean intermittent self-catheterizations were recommended to patients with persistent large RU.

Follow-up visits were scheduled at 1-week, 1-month, 3-months, 6-months, 1-year and annually thereafter. POP-Q evaluation on each patient were done. UDS were performed at 6–12 months post-operatively. Questionnaires were completed at 1 year and then annually post-operatively.

Outcome measures

The primary outcome measures were the objective cure rate which was defined as stage ≤1 prolapse at anterior or apical vaginal wall and all other compartments at 3-year after surgery. Subjective cure rate based on the patient negative feedback to question 2 (no or mild heaviness) and 3 (no or mild abdominal organ falling sensation) in POPDI-6 questionnaire [5]. The secondary outcome measures were the changes in quality of life that were assessed by the self-administered questionnaires patients were asked to complete. Peri- and postoperative complications were also recorded. Bladder outlet obstruction (BOO) was defined as peak flow rate (Qmax) of 15 ml/s or less and a detrusor pressure at maximal flow (Dmax) of 20 cm H_2O or more [10].

Statistical analysis

Descriptive statistics were used for the demographics and preoperative data. Student t-test was applied for comparison of continuous data. Intergroups comparisons were made for categorical variables using the chi-square or Fisher's exact tests. When the assumption of the chi-square test was violated (i.e., when > 1 cell had an expected count of <1 or >20% of the cells had an expected

count of <5), the Fisher's exact test was used. Comparisons on Questionnaires' scores were performed using the Mann–Whitney test. $p < 0.05$ was considered statistically significant for all comparisons. In order to detect 15% differences in the outcomes with 95% confidence level, sample size required for each groups were 62 subjects. Commercial software SPSS v.17 was used in all statistical analysis.

Results

One hundred thirty nine women were eligible, 10 patients were excluded from the study as they were unable to comply with the follow-up, 65 from Taipei and 64 from Linkou consented to be recruited. All women underwent the designated procedures; however, 2 patients failed to do UDS at 6–12 months due to transportation problems and 8 patients (4 from each group) did not turn up for their third year assessment. Attempts to contact the patients were made. However, due to various logistic reasons patients were not able to come for follow-up. Total of 119 patients were included for final analysis; 59 from Taipei and 60 from Linkou.

Demographic data of patients in both groups were as shown in Table 1. The mean operating time in SIM-A was longer than in SSF; (62.3 ± 21.4 min) and (53.1 ± 15.6 min); reaching a significant $p < 0.001$. Thus, the mean blood loss which affects the mean hemoglobin difference, both were more in the SIM-A group than SSF group, but none of the women required blood transfusion. There were no major organ injuries during the surgery. The immediate post-operative period was uneventful for most of the patients in both groups except for one from SSF group who had an operative site infection, which was treated with antibiotic.

UDS at 6–12 months follow-up, 18 (28.6%) women in the SIM-A group developed postoperative USI, while in the SSF group, 5 out of 64 (7.8%), $p = 0.002$ (Table 2). Eight out 23 patients, who had post-operative de novo SUI; 7 (10.8%) from SIM -group and 1 (1.6%) from SSF group, ($p = 0.030$) had undergone interval anti-incontinence procedure (Table 1).

Comparison between other UDS parameters (Table 2) showed decrease in the mean urethral closure pressure (MUCP) after surgery in both groups. However, the reduction was greater in the SIM-A compared to SSF, 77.8 ± 37.1 cm H_2O preoperatively to 58.4 ± 26.2 cm H_2O after surgery in SIM-A; $p < 0.001$, while in SSF group, from 80.1 ± 39.2 cm H_2O to 77.2 ± 44.2 cm H_2O post-operation with $p = 0.650$. The MUCP postoperatively was significantly lower in the SIM-A compared to SSF. Functional urethral length (FUL) in both groups was lower post-operatively than the pre-operative values. However, only the measurement within SIM-A group showed statistical significance; 25.6 ± 6.3 mm vs. 22.9 ± 6.8 mm, $p \leq 0.001$. Dmax (detrusor pressure at maximal flow) in both groups showed significant changes post-operatively; SIM-A 25.3 ± 14.2 vs. 18.0 ± 14.9 cm H_2O; $p < 0.001$; SSF 26.1 ± 15.1 vs 17.8 ± 15.1 cm H_2O; $p < 0.001$ but no significant difference between groups (Table 2). Both maximum flow rate (Qmax) and RU improved significantly postoperatively with no significant difference between groups. None of the women within both groups had evidence of bladder outlet obstruction (BOO) in their UDS' interpretation after surgery, which was originally found in 15 (25.4%) in SIM-A and 14 (23.0%) in the SSF group, and found to be significantly different within the groups themselves, $p < 0.001$, $p < 0.001$, respectively.

Table 3 illustrates the third-year follow-up of POP-Q that showed statistically significant differences in the intergroup comparison of pre- and post-operative values of points Aa, Ba and C. This indicates an advantage for the Elevate-A anterior repair. Point C, where the preoperative position showed statistically significant difference between the two arms (8.1 ± 3.9 cm for SIM-A, 6.9 ± 2.9 cm for SSF, $p \leq 0.001$). It is reflected on the 3-year post-operative analysis of this point that it seems to maintain a deeper position in Elevate-A than in SSF (pre- and postoperative 3-year difference: 18.2 ± 3.9 cm for SIM-A vs. 14.9 ± 4.4 cm for SSF, $p \leq 0.001$). Analysis of other POP-Q points showed no significant differences.

In Table 4, comparing the 3-year anatomical cure rate, patients in SIM-A had a significantly higher success rate in the anterior and apical compartment (96.6% vs. 73.3% $p < 0.001$; 98.3% vs. 85.0% $p = 0.009$) and in the overall prolapse correction rate according to the POP-Q (89.8% vs. 73.3%, $p = 0.020$) but a comparable success rate in the posterior compartment (89.8% vs. 81.7%, $p = 0.203$). Recurrences were observed in the anterior, apical and the posterior compartments with three patients (4.7%) from SSF group who required secondary pelvic reconstructive surgery adopting TVM post operatively, (Table 1).

Both procedures showed an improvement in the quality of life for the patients based on their recorded scores but the overall scores revealed no significant differences between the two arms at 3-year post-operation (Table 5). Comparing the 3-year subjective cure rates, patients in SIM-A had a significantly higher success rate (86.4% vs. 70.0%, $p = 0.030$) and in the lower overall POPDI-6 scoring (9.6 ± 2.9 vs. 11.5 ± 2.8, $p = 0.020$).

For sexually active patients, more sexual satisfaction was achieved after both surgeries with statistically significant difference in the mean PISQ-12 score (Pre-op: SIM A 23.7 ± 6.7, SSF 24.7 ± 7.4, Post-op: 28.3 ± 5.7, 29.4 ± 4.9, respectively), $p = 0.001$ within groups and $p = 0.516$ between groups (Table 5).

Cumulative cure rates and time to prolapse recurrence of both groups were illustrated in Fig. 1 for overall compartment and Fig. 2 for individual compartments. Both showed better cure rates for SIM-A than SSF over the 3 year period.

Discussion

Our study demonstrates that both the anterior and apical compartment objective cure rates in SIM-A group were significantly higher (96.6% and 98.3%) in comparison to the SSF group (73.4% and 85.0%). The overall objective cure rate also showed SIM-A group to be significantly better than SSF group with 89.8% success compared to 73.3%. This implies that the use of this mesh has a promising 3-year anatomical outcome in managing POP, overall and mainly at the anterior/apical compartment. In contrary, no significant differences were found in the anatomical cure rates between the two groups at the posterior wall compartment repair. These findings are consistent with a recent study comparing the single incision mesh repair versus traditional native repair for POP, which showed that the use of Elevate ^{TM} mesh kit had better one-year anatomical cure rate in restoring the anterior compartment prolapse than the traditional repair but with comparable success at the apical and posterior compartments [8]. Our results also showed significant improvement on the apical compartment. Reviewing literature for single arm studies that evaluated the efficacy of Elevate anterior mesh in management of anterior and apical prolapse, our results support their findings that this TVM kit has a high anatomical success rate at these compartments at one year follow-up [11–13].

During follow-up, it was found that point C in the SIM-A group was significantly deeper cranially compared to SSF. The possible reason for this observation is the fibrogenesis effect of the mesh on the SSL which was seen in the study of Azaïs H et al. using this kit [11], but not observed in our study. This might explain the vaginal lengthening seen with the use of this mesh. In a recent published study, Brennand EA et al. described a cranio-caudal movement of the anchoring tip of the Elevate single incision kit in 10/20 patients

Table 1
Patient demographics.

	SIM- A	n = 65	SSF	n = 64	p value
Mean age (year)	66.2 ± 8.1	(62.1–70.2)	63.1 ± 11.4	(54.1–69.1)	0.146
Median parity	3.4 ± 1.6	(2.7–3.6)	3.2 ± 1.7	(2.5–3.5)	0.436[a]
Mean BMI (kg/m^2)	26.0 ± 3.0	(21.9–25.0)	25.2 ± 3.3	(23.0–25.4)	0.254[a]
Postmenopausal status (*n*)	55	(76.9%)	53	(76.6%)	0.782*
Hormone therapy (*n*)	45	(69.2%)	44	(68.8%)	0.953*
Systemic	0	(0%)	2	(4.5%)	
Topical	45	(100%)	42	(95.5%)	
Prior pelvic surgery	11	(16.9%)	7	(10.9%)	0.327*
LAVH	1		1		
AH	10		6		
Cardiovascular diseases (*n*)	6	(9.2%)	5	(7.8%)	0.773*
Coronary heart disease (*n*)	2	(33.3%)	2	(40%)	
Stroke (*n*)	1	(16.7%)	1	(20%)	
Cardiac dysrhythmias (*n*)	3	(50%)	2	(40%)	
Hypertension (*n*)	25	(38.5%)	24	(37.5%)	0.910*
Diabetes (*n*)	12	(18.5%)	12	(18.8%)	0.966*
Primary surgery (n)					
VTH	50		56		0.117*
Cerix trachelectomy	1		2		0.546**
OP time, (min)	62.3 ± 21.4	(55.5–67.6)	53.1 ± 15.6	(50.7–58.8)	<0.001[a]
Intra-OP BL (ml)	105.4 ± 98.9	(76.0–128.4)	81.2 ± 89.5	(60.8–101.2)	<0.001[a]
Hb Difference (g/dL)	−1.4 ± 1.1	(-1.9–1.0)	−0.9 ± 1.0	(-1.2–0.7)	<0.001[a]
Hospital stay (days)	4.5 ± 0.8	(4.2–4.7)	4.4 ± 1.1	(4.2–4.6)	0.534[a]
Follow up period (months)	47.4 ± 7.2	(36.1–58.9)	48.2 ± 14.7	(36.4–59.7)	0.364[a]
Obj. cure at 3rd year	53/59	(89.8%)	44/60	(73.3%)	0.020*
Sub. Cure at 3rd year	51/59	(86.4%)	42/60	(70.0%)	0.030*
Complications, total	10	(16.1%)	6	(8.6%)	0.647*
Complications, major					
Organ injury	0		0		
Complications, minor	15	(23.1%)	9	(14.1%)	0.188*
Mesh exposure, vagina	0	(0%)	0	(0%)	*
Infection	0		1	(1.6%)	0.496**
Hb difference >2 (g/dL)	8	(3.1%)	3	(4.7%)	0.206**
Anemia with transfusion	0		0		
Other complications	0		0		
Secondary surgery (SUI, MUS sling)	7	(10.8%)	1	(1.6%)	0.030**
Secondary surgery (POP; TVM, Pessary)	0		3	(4.7%)	0.119**

SIM- A, single incision mesh-anterior (Elevate anterior); SSF, sacrospinous ligament fixation; BMI, body mass index; LAVH, laparoscopic assisted vaginal hysterectomy; AH, abdominal total hysterectomy; VTH, vaginal total hysterectomy; OP, operation; Intra-OP; BL, intra-operative blood loss; Obj, objective; Sub, subjective; SUI, stress urinary incontinence; MUS, mid-urethra sling; TVM, trans vaginal mesh; POP, pelvic organ prolapse; trans-vaginal mesh.
Data listed as mean ± standard deviation with 95% CI in parentheses or 100 percentile within parentheses.
[a]Un-paired t test; *Chi-Square Tests. **Fisher's exact test.

Table 2
Urodynamic data pre & post-operatively at 6 months.

	Pre-OP			Post-OP			Within group	
	SIM-A n = 63	SSF n = 64	P Between group	SIM-A n = 63	SSF n = 64	P Between group	SIM-A P	SSF P
Qmax	16.9 ± 8.1 (15.1–18.8)	17.1 ± 8.3 (15.3–21.0)	0.325[a]	20.3 ± 8.7 (16.6–23.5)	21.1 ± 10.6 (17.5–25.2)	0.815[a]	**<0.001***	**<0.001***
RU	71.9 ± 104.1 (48.2–123.1)	76.7 ± 91.2 (50.1–102.4)	0.268[a]	38.1 ± 37.4 (25.8–56.4)	40.7 ± 49.5 (35.2–57.2)	0.273[a]	**<0.001***	**<0.001***
CC	406.5 ± 118.2 (368.1–492.1)	401.1 ± 101.3 (361.5–516.1)	0.758[a]	395.1 ± 124.2 (346.0–459.2)	425.4 ± 134.0 (354.4–461.3)	0.314[a]	0.517*	0.241*
MUCP	77.8 ± 37.1 (68.3–96.1)	80.1 ± 39.2 (71.3–96.2)	0.447[a]	58.4 ± 26.2 (52.5–68.8)	77.2 ± 44.2 (67.6–89.1)	**<0.001**[a]	**<0.001***	0.650*
FUL	25.6 ± 6.3 (23.9–29.1)	25.7 ± 6.9 (23.0–29.4)	0.894[a]	22.9 ± 6.8 (19.2–26.2)	24.2 ± 5.6 (22.3–29.3)	**<0.001**[a]	**<0.001***	0.904*
Dmax	25.3 ± 14.2 (21.2–30.5)	26.1 ± 15.1 (22.0–31.4)	0.416[a]	18.0 ± 14.9 (14.2–22.1)	17.8 ± 15.1 (13.1–21.4)	0.615[a]	**<.000***	**<.000***
USI	0	0		18 (28.6%)	5 (7.8%)	0.002*		
DO	5 (8.5%)	3 (4.9%)	0.492**	1 (1.7%)	0 (0.0%)	0.496**	0.207**	0.244**
DO with incompetent urethral closure mechanism	4 (6.8%)	3 (4.9%)	0.718**	2 (3.4%)	2 (3.3%)	1.000**	0.680**	0.648**
BOO	15 (25.4%)	14 (23.0%)	0.795	0 (0.0%)	0 (0.0%)		<0.001**	<0.001**
DU	3 (5.1%)	2 (3.4%)	0.680**	3 (5.1%)	1 (1.3%)	0.365**	1.000**	0.559**

Qmax, maximum urinary flow; RU, post-void residuals; CC, cystometric capacity; MUCP, maximum urethral closure pressure; FUL, functional urethral length; MFR, maximal flow rate; Dmax, detrusor pressure at maximum flow; USI, urodynamic stress incontinence; DO, detrusor overactivity; BOO, bladder outflow obstruction; DU, Detrusor underactivity.
Data listed with percentage % in parentheses.
[a]Un-paired t test; *Pair-t test.
Chi–Square Tests; **Fisher's exact test.

Table 3
Pelvic organ prolapse quantification measurement at pre-operative and post-operative follow-up (3 years) according to surgical methods.

	Elevate A (n = 59)		SSF (n = 60)		p value[a]
	Pre-	Post-OP 3 year Difference between pre-OP and post-OP 3rd year	Pre-	Post-OP 3 year Difference between pre-OP and post-OP 3rd year	
Aa	1.6 ± 1.3 (1.3–1.8)		1.5 ± 1.3 (1.1–1.8)		0.381
		−2.7 ± 0.4 (−2.9–2.4)		−2.2 ± 0.9 (−2.7–1.9)	**0.012**
		4.3 ± 1.2 (3.8–4.6)		3.7 ± 1.4 (3.2–4.3)	**<0.001**
Ba	8.7 ± 3.2 (7.8–9.5)		7.3 ± 3.3 (5.53–6.65)		**<0.001**
		−2.7 ± 0.5 (−2.9–2.5)		−1.8 ± 1.0 (−2.1–1.5)	**<0.001**
		11.4 ± 3.1 (9.1–13.6)		9.1 ± 2.6 (7.5–11.6)	**<0.001**
C	8.1 ± 3.9 (7.1–9.1)		6.9 ± 2.9 (5.9–7.8)		**<0.001**
		−10.0 ± 1.3 (−11.3–9.3)		−8.0 ± 1.1 (−9.5–6.75)	**<0.001**
		18.2 ± 3.9 (16.2–19.8)		14.9 ± 4.2 (12.1–17.2)	**<0.001**
Ap	0.3 ± 1.1 (0.1–0.59)		0.4 ± 1.3 (0.2–0.8)		0.201
		−2.4 ± 0.7 (−2.7–2.2)		−2.3 ± 0.9 (−2.7–2.3)	0.816
		2.7 ± 1.4 (2.4–3.31)		2.9 ± 1.5 (2.4–3.6)	0.541
Bp	6.6 ± 2.8 (5.5–7.6)		6.4 ± 2.6 (5.2–7.4)		0.139
		−2.3 ± 0.7 (−1.9–2.6)		−2.1 ± 1.0 (−1.8–2.5)	0.616
		8.9 ± 2.9 (7.81–9.71)		8.5 ± 2.7 (7.7–9.5)	0.261
D	7.0 ± 3.3 (5.7–8.2) n = 59		6.0 ± 2.9 (4.4–7.2) n = 60		**0.029**
TVL	11.7 ± 1.7 (11.3–12.3)		10.7 ± 1.7 (10.6–11.0)		0.426
		10.7 ± 13 (10.2–11.0)		9.6 ± 1.5 (8.8–10.9)	0.673
		−1.0 ± 1.2 (−0.8–1.4)		−1.1 ± 1.0 (−0.8–1.4)	0.138
Gh	4.7 ± 0.9 (4.5–5.0)		4.6 ± 0.5 (4.4–5.1)		0.591
		4.9 ± 0.5 (4.7–5.3)		4.9 ± 0.56 (4.6–5.8)	0.863
		−0.2 ± 0.7 (−0.1–0.3)		−0.3 ± 0.48 (−0.1–0.3)	0.153
Pb	2.0 ± 0.2 (1.7–2.3)		2.0 ± 0.8 (1.7–2.4)		0.843
		2.1 ± 0.4 (2.0–2.3)		2.2 ± 0.84 (2.0–2.3)	0.247
		0.1 ± 0.3 (0.0–0.2)		0.2 ± 0.60 (0.1–0.2)	0.217

Aa anterior wall 3 cm from hymen; *Ap* posterior wall 3 cm from hymen; *Ba* anterior wall, most dependent par (cm); *Bp* posterior wall, most dependent par (cm); *C* cervix or vaginal cuff (cm); *D* posterior fornix (if cervix is present) (cm); *Gh* genital hiatus, meatus to fourchette (cm); *Pb* perineal body, posterior fourchette to mid anus (cm); *TVL* total vaginal length (cm).
Data listed as mean ± standard deviation with 95% CI in parentheses.
[a] Un-paired t test.

who underwent this surgery where ≥4 mm change in location was observed in 8/10 at 6 months after the operation using MRI. This movement was noticed less frequently among the SSL anchors than other pelvic structures anchors, which were seen in 10/20 patients. Their observation might explain the recurrence in the anterior compartment in some cases and also the C point upward migration [14].

Comparing the safety of both procedures, our study showed that Elevate-A is associated with a significant higher risk of intra-operative blood loss, but none of the patients required blood transfusion, and a longer operative time than SSF, despite that more patients within SIM-A group had previous hysterectomy, which in contrary should shorten the time of surgery.

No significant differences were found between the two arms in terms of the length of hospital stay period and follow-up periods. No injury to surrounding organs was reported. No mesh erosion occurred within SIM-A group. Lo et al. reported same rate in their recent study with this TVM kit [15], in comparison to previous literature which includes either single arm (Elevate ™ or Elevate-A alone) or two arms studies where the rate was higher [11–13,16,17].

In this study, significant improvement in terms of quality of life including lower urinary tract and prolapse symptoms was achieved postoperatively within each group but had no significant difference between groups (Table 5). Except for POPDI-6 which showed significant differences between the two groups. For sexual function, 28.8% of women in the SIM-A and 31.7% in the SSF were sexually active pre-operatively which is because patients in Elevate-A were older than the SSF, and overall, these women reported significantly higher sexual satisfaction after surgery with no better trend toward any of the groups. Previous studies yielded different results

Table 4
Pelvic organ prolapse quantification (POP-Q) staging at pre-operative and post-operative follow-up (3 years) according to surgical methods.

Type of prolapse	Anterior		Apex		Posterior		Overall	
Stage	EL, n = 59 Pre-OP/Post-OP	SS, n = 60 Pre-OP/Post-OP	EL, n = 59 Pre-OP/Post-OP	SS, n = 60 Pre-OP/Post-OP	EL, n = 59 Pre-OP/Post-OP	SS, n = 60 Pre-OP/Post-OP	EL, n = 59 Pre-OP/Post-OP	SS, n = 60 Pre-OP/Post-OP
0	0/55	0/33	0/57	0/42	0/46	0/40	0/46	0/33
1	0/2	0/11	0/1	0/9	0/7	0/9	0/7	0/11
2	5/2	6/10	0/1	3/6	8/4	4/7	0/4	0/10
3	36/0	38/6	40/0	40/3	35/2	40/4	40/2	41/6
4	18/0	16/0	19/0	17/0	16/0	16/0	19/0	19/0
Failure rate	3.4%	26.7%	1.7%	15.0%	10.2%	18.3%	10.2%	26.7%
*Failure	2	16	1	9	6	11	6	16
p value		<0.001**		0.009**		0.203		0.020

Pre-OP, pre-operation; Post-OP, post-operation.
* Failure, stage >1 prolapse at specific vaginal compartment.
Chi–Square Tests; **Fisher's exact test.

Table 5
The UDI-6, IIQ-7, POPDI-6 and PISQ-12 scores pre and post surgery at 3 year.

		SIM A (n = 59)	SSF (n = 60)	p value (between group)
UDI-6	Pre-	13.4 ± 3.9 (12.3–14.4)	15.0 ± 5.5 (13.7–16.4)	0.161
	Post-	10.4 ± 2.6 (9.7–11.1)	10.0 ± 2.7 (9.32–11.5)	0.256
p value (within groups)		**<0.001**	**<0.001**	
IIQ-7	Pre-	12.5 ± 4.0 (11.4–13.6)	13.3 ± 4.1 (12.5–14.8)	0.196
	Post-	7.5 ± 2.0 (6.9–7.9)	8.0 ± 1.7 (7.0–8.9)	0.311
p value (within groups)		**<0.001**	**<0.001**	
POPDI-6	Pre-	14.6 ± 6.2 (12.9–16.1)	14.0 ± 6.7 (12.6–15.0)	0.481
	Post-	9.6 ± 2.9 (8.5–10.7)	11.5 ± 2.8 (10.3–13.5)	**0.020**
p value (within groups)		**<0.001**	**<0.001**	
PISQ-12	Pre-	23.7 ± 6.7 (19.7–27.5) n = 17 (28.8%)	24.7 ± 7.4 (20.6–28.7) n = 19 (31.7%)	0.148
	Post-	28.3 ± 5.7 (25.9–33.1) n = 17 (28.8%)	29.4 ± 4.9 (26.7–35.1) n = 19 (31.7%)	0.516
p value (within groups)		**0.001**	**0.001**	

UDI-6, Urinary Distress Inventory (score 0–18); IIQ-7, Incontinence Impact Questionnaire (score 0–21); POPDI-6, Pelvic Organ Prolapse Distress Inventory 6 (score 0–24); PISQ-12, Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (score 0–48).
Data listed as mean ± standard deviation with 95% CI in parentheses.
Bold letters are statistically significant p values.

regarding the sexual function after Elevate (either Elevate™ or Elevate-A) with some showing improvements [13], others no change [11], and when searching the literature for the effect of using trocar-guided mesh kit on sexual function, conflicting results were found with some showing increased risk of dyspareunia [18,19], others with no improvement [20], or improvement in this symptom [21]. Same possibilities were found when use of vaginal mesh was compared to anterior colporrhaphy [8,18].

UDS demonstrated a decrease in the postoperative MUCP within both groups but it was significantly lower in SIM-A patients ($p < 0.0001$) in comparison to SSF, with a statistically significant difference between them ($p < 0.001$). Multiple factors might affect this findings. 1.)Women in the Elevate-A group by their mean age were older than those in SSF arm (Table 1), and MUCP had an inverse relationship with age [22]. 2.)The opening and the extensive dissection of the para-vesical space during Elevate-A arms insertion may lead to nerve injury with denervation of the pelvic striated muscle which supports the bladder and urethra that may cause urethral hypermobility and which was also found to decrease the MUCP. This might explain the significant increase in USI in SIM-A patients after the surgery, as the elements for proper urethral function and urine continence are high MUCP and absence of hypermobility [22–24]. Our results in respect to MUCP are consistent with UDS showing significantly lower MUCP after use of a TVM kit, as compared with colporrhaphy [25].

USI was seen more after the Elevate-A procedure than SSF (28.6% vs. 7.8%, $p = 0.002$), only 38.8% (7/18) USI of SIM-A developing patients required secondary intervention with MUS, because,

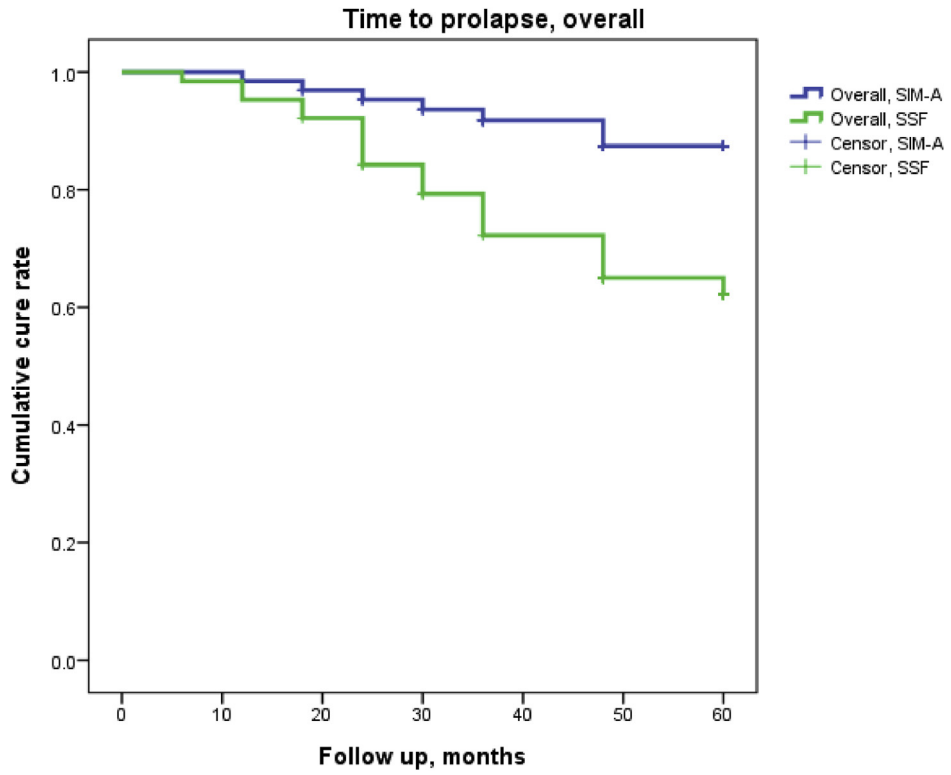

Fig. 1. Time to prolapse for overall compartments overall. Kaplan Meier Survival for cumulative incidence of prolapse-free after SIM-A and SSF surgery for patient with advanced pelvic organ prolapse. Mantel-Haenszel log rank test, $p = 0.003$.

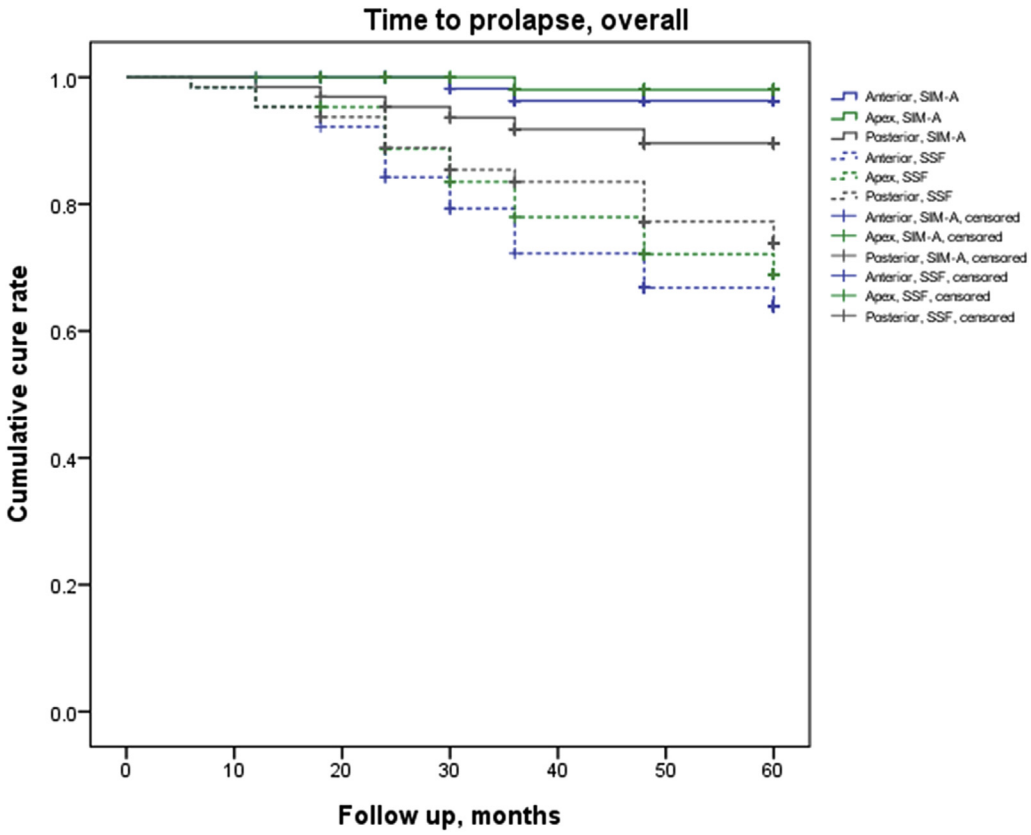

Fig. 2. Time to prolapse for anterior, apical, and posterior compartments. Kaplan Meier Survival for cumulative incidence of prolapse-free on anterior, apical and posterior compartment after SIM-A and SSF surgery for patient with advanced pelvic organ prolapse. Mantel-Haenszel log rank test, $p < 0.001$ (anterior); $p < 0.001$ (apical); $p = 0.055$ (posterior).

postoperative feedback to question 3 in UDI-6 questionnaire showed significant improvement (mean pre-op 13.4 vs. mean post-op 10.4, $p < 0.001$) with no increase in the bothersome lifestyle.

Using Chassagne S et al. for diagnosis of BOO [10], it was found that 25.4% of SIM-A group and 23.0% in SSF group had BOO pre-operatively. After surgery, there was marked improvement (0%) in both groups with statistically significant difference within the groups, as what is expected after correction of the prolapse.

Our study has its limitations. Patients were not randomly allocated. It is relatively a small cohort and has short follow-up period. The major strength is the good patient's follow-up and that all procedures were performed by the same experienced surgeon which may reflect the homogeneity of the surgical results.

In conclusion, the use of Elevate anterior/apical prolapse repair system, SIM-A showed better objective cure rate at the anterior/apical vaginal compartment, the overall prolapse correction and a favorable subjective prolapse repair outcomes in comparison to SSF 3 years after the surgery but with less significant difference in quality of life. Larger size and longer follow up period studies are recommended to support this result.

Authors' contribution

TS Lo: Protocol/Project development, Data collection, Data analysis, Manuscript editing; financial disclaimer/conflict of interest: none.

AM Al-Kharabsheh: Data analysis, Manuscript writing/editing; financial disclaimer/conflict of interest: none.

YL Tan: Data analysis, Manuscript writing/editing financial disclaimer/conflict of interest: none.

LB Pue: Data analysis, Manuscript writing/editing financial disclaimer/conflict of interest: none.

WC Hsieh: Data analysis, Manuscript writing/editing financial disclaimer/conflict of interest: none.

MC Patrimonio: Manuscript writing/editing financial disclaimer/conflict of interest: none.

Conflicts of interest

None.

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