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ORIGINAL ARTICLE

Anterior–apical Transvaginal Mesh (Calistar-S) for Treatment of Advanced Urogenital Prolapse: Surgical and Functional Outcomes at 1 Year

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Abstract

Introduction and hypothesis Calistar-S is a single-incision synthetic mesh kit that addresses apical and anterior compartment prolapse. The aims of this study were to evaluate the short-term objective and subjective outcomes at the 1-year follow-up. The secondary objectives were to evaluate quality of life and lower urinary tract symptoms (LUTS) outcomes, as well as surgical complications.

Methods Records of 108 patients with symptomatic advanced pelvic organ prolapse (stages III and IV) who underwent prolapse surgery using the Calistar-S system from June 2018 to August 2022 were reviewed. The primary outcome was the objective cure of anterior and apical prolapse < stage 1, and the subjective cure was the negative response to questions 2 and 3 of the Pelvic Organ Prolapse Distress Inventory-6. Secondary outcomes measured quality of life, the presence of lower urinary tract symptoms, and complications.

Results A total of 101 patients were evaluated. The overall objective cure rate is 97% and the subjective cure rate is 92.1%. Good outcomes were seen in all three compartments. Secondary outcomes show significant improvement in all validated questionnaires. Persistence and de novo urinary incontinence were 15.2% and 18.2% post-operatively. There is one case of bladder injury and one case of vaginal mesh exposure.

Conclusions The Calistar-S System is a safe and efficient method for treating advanced-stage POP. We observed good anatomical results and subjective relief with a minimal complication rate. LUTS have also been positively affected, showing a high success rate. Additional studies are needed to establish the long-term efficacy of this system.

Keywords Anterior–apical repair · Calistar-S · Mesh complication · Pelvic organ prolapse · Transvaginal mesh

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Introduction

Pelvic organ prolapse (POP) affects 3–6% of the population [1], and according to a US survey, the lifetime risk of any primary surgery for stress urinary incontinence (SUI) or POP was 20.0% by the age of 80 [2]. The pathophysiology of POP is complex and involves tissue damage and innervation to the pelvic floor muscles and connective tissue. Surgical treatment is aimed at restoring the correct anatomy and function of the pelvic floor.

Advanced POP involves all three compartments of the vaginal wall. In order to achieve optimal anatomical correction, establishing apex support is essential [3]. However, in cases of apical suspension to the sacrospinous ligament (sacrospinous ligament fixation [SSLF]) or the uterosacral ligament (uterosacral ligament fixation), with the use of native-tissue repair, there is a large incidence of anterior compartment recurrence [4, 5]. Therefore, preventive reconstruction and support of the anterior compartment are necessary.

Synthetic non-absorbable vaginal mesh kits with the SSLF feature, such as the Elevate-A (Elevate Anterior and Apical Prolapse Repair System, American Medical Systems, Minnetonka, MN, USA) and Uphold-lite (Boston Scientific, Marlborough, MA, USA), both single-incision systems, were introduced to address this issue. These mesh kits, designed for apical and anterior suspensions, showed objective cure rates of 94 to 98% in short- and long-term follow-up [6, 7]. Thus, good tension may be achieved, and deformity of the vagina could be avoided [8].

Calistar-S (Promedon, Córdoba, Argentina) is a single-incision mesh kit that is similar in concept to the SSLF (i.e., apical and anterior support). The mesh is made from macroporous monofilamentous polypropylene. It consists of a central part with a large pore size of up to 4 mm and an outer frame with smaller pores of 0.8 mm in size. It has two anterior attachment arms and two posterior ones, aimed at the internal obturator muscle and the sacrospinous ligament (SSL) respectively. The mesh is attached via the tissue-anchoring system (TAS), composed of a polypropylene anchor with six circumferentially arranged polypropylene spikes [9]. So far, there are limited data regarding the efficacy and safety profile of this kit [10, 11].

In 2019, the Food and Drug Administration (FDA) banned US sales of pelvic mesh owing to concerns about a lack of long-term follow-up data on their effectiveness compared with native tissue repair and safety outcomes, together with insufficient evidence that the probable benefits of transvaginal mesh surgery outweigh their risks. Since then, vaginal mesh kits have no longer been available on the US market. Nevertheless, in Asian countries, including Taiwan, the use of vaginal mesh is acceptable for selected patients [12].

The aims of this study were to evaluate the objective and subjective outcomes of POP treatment using the Calistar-S system. The secondary objectives were to evaluate quality of life (QOL) and lower urinary tract symptoms (LUTS) outcomes, in particular de novo or persistent urodynamic stress incontinence (USI), as well as surgical complications.

Materials and Methods

This is a descriptive retrospective study, performed in a tertiary referral center with a urogynecology division, which was approved by the Institutional Board Review (IRB: 202301330B0). The medical records of 108 patients with symptomatic advanced POP (Pelvic Organ Prolapse Quantification [POP-Q] stages III and IV) [13] who underwent pelvic reconstructive surgery using the Calistar-S system between June 2018 and August 2022 were reviewed. Symptomatic POP was defined as a complaint relating to a bothersome vaginal bulge or other prolapse-related symptoms, confirmed by a physical pelvic examination. Patients with previous radical pelvic surgeries or prior mesh installment for prolapse, or those who were medically unfit for surgery, were excluded. Patients with medical comorbidities were addressed preoperatively by anesthetists and physicians, including a requirement of glycated hemoglobin of 6.9% and below for the preceding 3 months.

Pre-operative Evaluation

All the participants had preoperative clinical assessments according to institutional protocol [6]. It included a detailed medical history, a physical and pelvic examination, a cough stress test, a 1-h pad test, a 3-day voiding diary, and multichannel urodynamic testing. Prolapse staging was recorded based on the POP-Q system [13]. For quality-of-life evaluation, we used validated Chinese questionnaires that were completed by all patients at baseline and at 6 and 12 months post-operatively. The questionnaires were Urogenital Distress Inventory 6 (UDI-6), Incontinence Impact Questionnaire 7 (IIQ-7) [14], Pelvic Organ Prolapse Distress Inventory (POPDI-6) [15], and Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire 12 (PISQ-12) [16]. All the conditions were defined according to the standards of the International Urogynecological Association/International Continence Society [13]. Participants who chose uterus preservation underwent endometrial assessment using transvaginal ultrasound and endometrial sampling, if indicated, before surgery. SUI was based on the clinical symptoms, which were confirmed by a cough stress test and a multichannel urodynamic evaluation. These tests were performed with the patient in a semi-lithotomy position

with the prolapse reduced. USI was defined as involuntary leakage of urine during increased intra-abdominal pressure in the absence of detrusor contraction on filling cystometry. Occult SUI was considered for patients with urine leakage that appeared after the prolapse was reduced during urodynamic evaluation without symptomatic SUI.

All patients had thorough counselling regarding treatment options (such as the conservative option or use of vaginal pessaries), uterine preservation versus concomitant hysterectomy, and potential benefits versus risks (possibility for intra- and post-operative complications, i.e., mesh-related concerns, de novo SUI, and risk of prolapse recurrence).

Vaginal estrogen treatment was offered to all of our patient, unless contraindicated.

Prior to participation in the study, written informed consent was obtained from all patients.

Patients who demonstrated USI during their preoperative workup were consulted and underwent concomitant mid-urethral sling (MUS) after signing informed consent.

Operative Procedure

All surgical procedures were performed by a single senior surgeon in the following order: vaginal hysterectomy (if indicated), administration of the Calistar-S system, posterior colporrhaphy, and trans-obturator MUS (if needed) through a separate incision on the anterior vaginal wall at the level of the mid-urethra.

For the application of the Calistar-S, the operative procedure followed the manufacturer's recommendations [9]. However, some modification was made in order to minimize the risk of anatomical failure of the anterior compartment and the development of cystocele: 1–0 Vicryl stitches were applied on the distal tip of the mesh through the bladder/vaginal mucosa under the bladder neck [6]. Standardized modification of the mesh implant is performed by trimming and removing the posterior semicircle segment of the mesh without compromising its integrity. The surgical procedure starts with a full-thickness hydro-dissection of the vesicovaginal space, followed by a midline vertical incision of the anterior vaginal wall, starting at the level of the bladder neck and moving towards the vaginal vault or cervix. Sharp and blunt dissection is done in the para-vesical space bilaterally until the ischial spines and SSLs are reached. The TAS with polypropylene sutures is then implanted using Retractable Insertion Guides (RIGs) approximately 2 cm medially from the ischial spine in the SSL, bilaterally. Implantation of anterior anchors is performed using sharp dissection toward the obturator foramen horizontally on both sides. The anterior arms are anchored using RIGs toward the internal obturator muscle. It is ensured that the mesh is not twisted and is positioned in a tension-free fashion, horizontally toward the bladder neck. The central part of the mesh is attached close to the bladder neck using an absorbable suture to prevent mesh displacement. The distal pores of the posterior arms are then attached to the previously anchored TAS, and the knot is secured at the SSL. Closure of the vaginal wall is then performed without excising the vaginal epithelium, even when redundant, using a 2–0 absorbable running suture. In cases where hysterectomy is performed concurrently, the distal part of the vaginal epithelium is sutured to the mesh to prevent a potential gap.

To assess the integrity of the lower urinary tract, cystoscopy was routinely performed after the procedure. As a prophylactic, 500 mg of cefazolin was given intravenously during the 60 min prior to the initial cut and then continued every 6 h for 24 h post-operatively. Foley's catheter was inserted at the beginning of the procedure and left in place for 24 h. Povidone–iodine-soaked gauze was packed in the vagina for 24 h.

Patients were discharged once they were able to void comfortably, and the sonographically post-void residual urine (PVRU) volume was consistently below 150 ml. The patients were also taught to use clean, intermittent self-catheterization if their PVRU volume was persistently above 150 ml for more than 5 days.

Patients were scheduled for outpatient follow-up visits at 1 week, 1, 3, 6, 12 months, and annually post-operatively. The evaluation included a detailed history, validated questionnaires, vaginal examinations, and PVRU measurement using sterile catheterization. A multichannel urodynamic study was done over a year.

Primary Outcomes

The preoperative and postoperative evaluations followed institutional protocol. The primary outcome was the objective cure rate, defined as anatomical correction of anterior, posterior, and apical prolapse of POP-Q ≤ Stage 1. Subjective primary outcome was defined as the patient's feedback to questions 2 and 3 of the POPDI-6 (heaviness or dullness in the pelvic area and sensation of POP respectively). Secondary outcomes included quality of life, which was assessed by validated questionnaires (UDI-6, IIQ-7, POPDI-6, and PISQ-12) at 12 months and annually postoperatively. Also evaluated were the presence of LUTS, in particular the presence of de novo and persistent SUI, and surgical complications. De novo and persistent SUI were assessed through a multichannel urodynamic study and a 1-h pad test. Telephone interviews by a credentialed nurse were held with patients unable to participate in clinical follow-ups.

Statistical Analysis

A post hoc sample size of 56 subjects was needed to detect de novo USI of 25%, with a 95% confidence interval and statistical power of 80%. Descriptive statistics were used for demographics and perioperative data. The paired-samples *t* test and the

McNemar test were applied for comparison of pre- and postoperative continuous and categorical data respectively. The distribution-based approach uses the effect size (ES) index to relate clinically meaningful change. The minimal major difference was calculated as the standard deviation (SD) = 0.2 (small ES), SD = 0.5 (medium ES), and SD ≥ 0.8 (large ES) of baseline scoring [17]. Values of $p < 0.05$ were considered statistically significant for all comparisons. All statistical analyses were performed using SPSS version 17 (IBM, Armonk, NY, USA; Fig. 1).

Results

As shown in Fig. 2, 108 patients had surgery with Calistar-S. Seven patients were excluded because of incomplete data, and 101 patients were included in our final analysis. Baseline demographic characteristics are shown in Table 1. The mean age was 67.1 ± 8.0 years, most of the patients (96%) were post-menopausal, 8 (7.9%) patients had undergone previous pelvic surgery, and the mean BMI was 24.7 ± 2.9 kg/m^2.

Intra-operative details are also displayed: the mean operating time was 61.4 ± 13.8 min, with a mean blood loss of 67.7 ± 56.8 ml. All patients underwent concurrent posterior colporrhaphy (100%), 35.6% ($n = 36$) had vaginal hysterectomy in the same setting, and 41.6% ($n = 42$) underwent a TOT procedure.

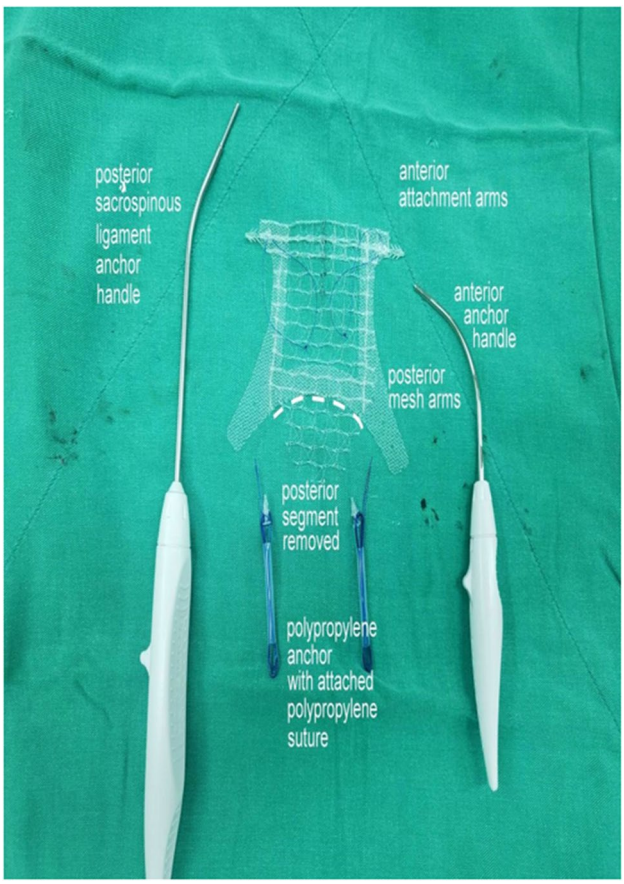

Fig. 1 Modification of Calistar-S mesh. Proximal end of mesh (posterior segment, tongue excised)

We encountered one case of intra-operative bladder injury that was discovered during pelvic dissections. It was repaired immediately, and the planned procedure was completed. A Foley catheter was left for 3 days. The follow-up revealed a satisfying recovery with no further adverse effects.

The mean follow-up duration was 18.7 ± 5.0 months. One patient presented with asymptomatic mesh exposure, which was diagnosed 2 months post-operatively during a routine follow-up meeting. Upon examination, 1 cm of exposure in the middle of the anterior colporrhaphy suture line was seen. The exposed mesh was trimmed in the operating room setting without complications, and follow-up was uneventful [18].

As shown in Fig. 3, the objective cure rate after 1 year showed complete anatomical correction for the apical and anterior compartments (100%) and 96% successful repair at the posterior compartment. Major improvement was seen at all anatomical points, according to the POP-Q score (Table 2), in addition to the statistically significant shortening of TVL (9.32 ± 1.53 cm vs 8.43 ± 0.68, $p < 0.01$, pre- and post-operatively respectively). The subjective cure rate was high (92.1%) at the end of the follow-up period. All validated QOL questionnaires (UDI-6, IIQ-7, POPDI-6, CRADI-8, and PISQ-12) scores at pre- and 1-year post-surgery showed significant improvement (Table 3).

As for the urodynamic parameters (Table 3, there was significant improvement in Qmax and Dmax. Cystometric capacity, maximum urethral closure pressure, and functional urethral length were decreased significantly. Bladder outlet obstruction (BOO) was resolved in all cases but one (39 out of 40). And 4 patients (4 out of 7, 57.1%) had their mixed urinary incontinence resolved after the surgery.

Detrusor overactivity and detrusor overactivity incontinence were not properly resolved (1 out of 4 cases and 1 out of 3 cases respectively). Out of the 42 patients with occult or overt USI who underwent an MUS procedure, 38 (90.5%) remained asymptomatic after 1 year. In contrast, 3 patients with overt pre-operative USI who chose conservative treatment had persistent USI. One patient with an occult pre-operative USI who refused to undergo concurrent MUS had her USI resolved. Ten cases of de novo SUI were recorded, which corresponds to 18.2% of the total cohort.

Discussion

To the best of our knowledge, the present study is the first of its kind to focus on the surgical management of patients with symptomatic advanced POP with the modified Calistar-S system using validated questionnaires and urodynamics

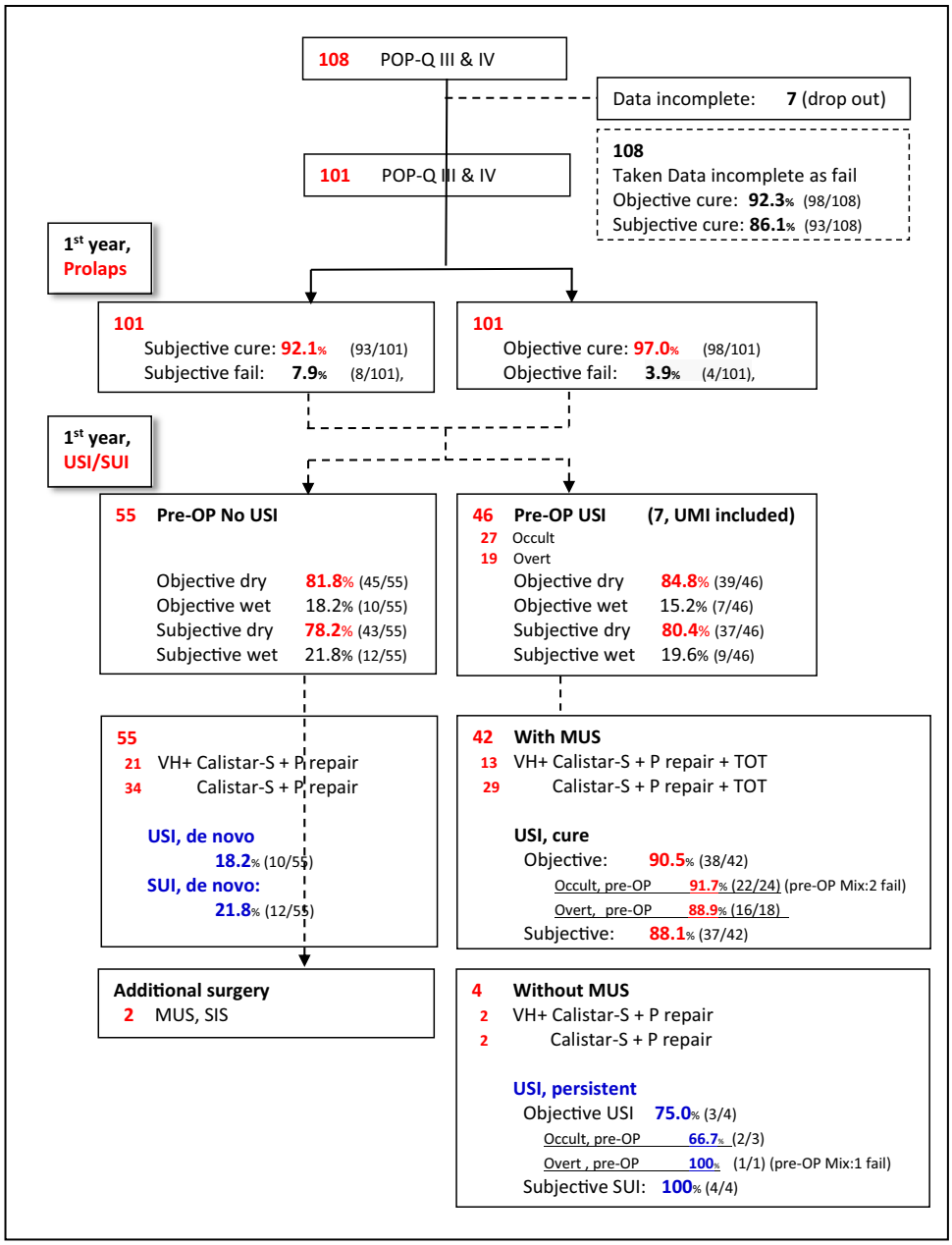

Fig. 2 Flow chart

and has demonstrated good 1-year objective and subjective outcomes. Our results are comparable with those of other commercial mesh kits such as Elevate-A and Uphold-Lite and (94% and 89.8 objective cure rate respectively) [6, 7]. In addition, significant improvement was noted in all validated QOL questionnaire results.

We have maintained close and regular follow-up, with a documented mesh exposure rate of 1%. Our complication rate is low compared with a large analysis by Nguyen et al., who found a 3% erosion rate after vaginal mesh surgeries in the USA. In that study, erosion was more frequent after mesh placement below the anterior vaginal wall [19]. There are a few possible explanations for that difference. First, a relatively low percentage of our patients (35.6%) had a concomitant hysterectomy, thus decreasing the damage to the vaginal tissue and contact between the mesh and vaginal cuff, leading to a lower chance of dehiscence. Also, the Calistar-S mesh, with its adequate total size and large pore size at the mesh center, may reduce the post-operative tissue reaction. Animal studies have shown that mesh size is directly proportional to the inflammatory reaction in the host tissue, which leads to delayed mesh-tissue integration [20].

A major risk factor for mesh erosion is intra-operative bleeding [21], although in our cohort the mean intra-operative blood loss was 67.7 ml. This may also contribute to a favorable outcome. Other risk factors were found to have been related to mesh exposure, such as smoking [21, 22] and diabetes [23]. In our cohort, none of the patients reported smoking, and all of them had HbA1c levels below

Table 1 Patients' baseline demographics and surgical outcomes ($N = 101$)

Demographic/surgical outcome		
Mean age (yeara)	67.1 ± 8.0	(65.5–68.7)
Median parity (range)	3.0	(1–9)
Mean BMI (kg/m^2)	24.7 ± 2.9	(24.1–25.3)
Postmenopausal	97	(96.0%)
Prior pelvic surgery	8	(7.9%)
LH	1	
TAH	4	
VH SS	1	
Burch urethropexy	1	
MUS (SIS, MiniArc)	1	
Mean operating time (min)	61.4 ± 13.8	(58.7–64.2)
Mean intraoperative blood loss (ml)	67.7 ± 56.8	(56.5–78.9)
Mean hemoglobin difference (g/dl)	1.07 ± 0.90	(0.83–1.28)
Mean hospital stay (days)	3.0 ± 0.2	(2.9–3.1)
Median period of follow-up (months)	18.7 ± 5.0	(17.7–19.6)
Concurrent surgery		
VH (*n*)	36	
MUS (TOT)	42	
Posterior colporrhaphy	101	
Complications,		
Bladder injury	1[a]	
Mesh exposure, vagina (*n*, %)	1[b]	(1.0%)
Objective cure on prolapse at 1 year (*n*, %)	97/101	(96.0%)
Anterior	101/101	(100%)
Apex	101/101	(100%)
Posterior	97/101	(96.0%)
Subjective cure on prolapse at 1 year (*n*, %)	93/101	(92.1%)

Data are listed as mean ± standard deviation with 95% CI in parentheses, median with range, or number with percentage within parentheses

BMI body mass index, *LH* laparoscopy hysterectomy, *TAH* total abdominal hysterectomy, *VH* vaginal hysterectomy, *SS* sacrospinous ligament fixation, *MUS* mid-urethral sling, *SIS* single-incision sling, *TOT* trans-obturator tape

[a]Injury at dissection; repair immediate; followed by Calistar-S surgery; Foley maintained for 3 days; Uneventful after surgery and to date

[b]The patient has an asymptomatic 1-cm exposure at the middle of the anterior colporrhaphy suture line, diagnosed 2 months postoperatively (2BT2S1). The mesh was trimmed. The follow-up was uneventful

6.9%. Last, all of the surgeries were performed by a single, well-experienced surgeon, which may have influenced our complication rate. Surgeon experience is a key factor in the occurrence of mesh complications [23] and there has been a negative linear association between the number of mesh operations performed and complications encountered [24].

Another beneficial effect of pelvic floor reconstructive surgery is restoring normal anatomy and resolving BOO. In our cohort, 39 out of 40 patients had relief of their symptoms, along with great improvement in their UDS parameters, at the end of the post-operative year. Urodynamic parameters of our patients revealed significantly elevated Qmax with reduced Dmax and PVR postoperatively, suggesting resolution of their voiding dysfunction.

The total number of USIs decreased 1 year post-operatively. Out of the 42 patients who chose to undergo MUS procedures, only 4 (9.5%) had persistent USI. This is comparable with the results of a previous study, with a 10.5% risk for persistence [25], but slightly higher than another, with a 5% risk [26]. One patient with pre-operative occult USI chose conservative treatment and resolved spontaneously. Three patients with pre-operative overt USI remained symptomatic after 1 year, supporting the benefit of concurrent MUS surgery. Two patients with pre-operative overt USI had secondary intervention for MUS within 12 months following the primary POP repair. The remaining two patients did not have severe symptoms to justify surgical intervention.

Ten new cases of urinary stress incontinence (de novo SUI), which represents 18.2% of the asymptomatic population, were recorded during the follow-up period. It is a slightly lower rate than published before in a review by van der Ploeg et al. and in other retrospective studies [6, 7, 27]. Paravesical space dissection during the surgical procedure may result in de novo or persistent SUI. The proposed mechanism is a tissue-inflammatory response and nerve damage [28, 29]. Adopting a more modest dissection of the paravesical space during mesh application, in comparison with large-scale dissection techniques, could have a desirable effect.

The Calistar-S offers a unique method of mesh deployment. It provides good apical support at the proximal part of the vagina. Anchoring is done to four points altogether, assuring strong and balanced support. Suspension to the sacrospinous ligament is done by applying direct palpation without visualization using the anchoring system. The modified addition of the Vicryl sutures to the distal end of the mesh below the bladder neck should have contributed to the good anatomical correction. The mesh arrangement, with large pores in the center and smaller ones in the outer part, reduces the overall mass and therefore the risk of tissue reaction. Specifically, there is less mesh mass over the incision site.

There were strengths and limitations to our study. We have used a standardized evaluation protocol using urodynamic studies and questionnaires, which mimic prospective case–control studies. In order to evaluate quality of life, we have used multiple validated questionnaires. In addition, the urodynamic study enabled us to get objective data and may help to shed some light on the effect of single-incision mesh surgery on bladder function. To limit the bias, a POP-Q evaluation was performed by at least one of the study members at the end of the follow-up period. We are also aware of our limitations. This was a single-arm retrospective study with

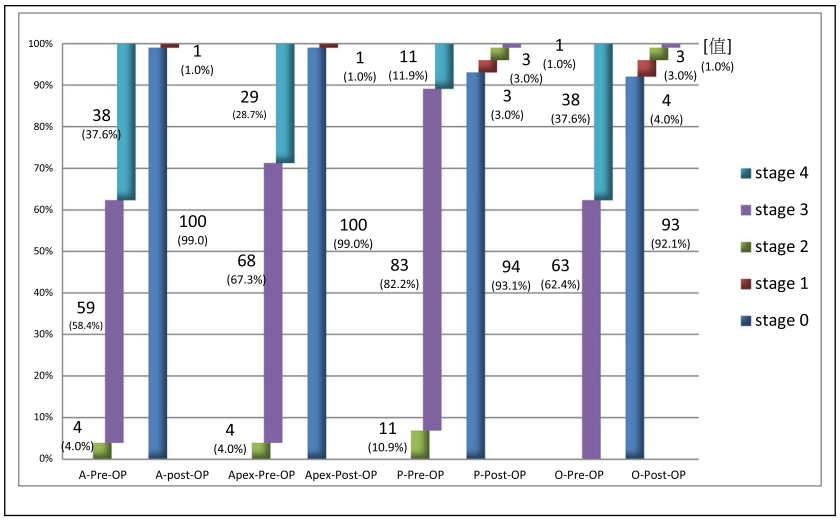

Fig. 3 Pelvic organ prolapse quantification (POP-Q) staging preoperatively and at the 1-year postoperative follow-up after anterior-apical single-incision mesh surgery (Calistar-S) in 101 patients

Table 2 Pelvic organ prolapse quantification measurement at pre-operative and post-operative follow-up according to surgical methods ($N=101$)

	Pre-operative	Post-operative 1 year	Difference between pre-operatively and post-operatively 1st year	*p* value [a]
Aa	1.30 ± 1.00 (1.10–1.50)	−2.88 ± 0.25 (−2.92 to 2.83)	*4.17 ± 1.02 (3.97–4.37)*	**< 0.001**
Ba	6.78 ± 2.24 (6.33–7.22)	−2.84 ± 0.26 (−2.89 to 2.79)	*9.62 ± 2.73 (9.17–10.07)*	**< 0.001**
C	6.26 ± 2.37 (5.80–7.73)	−7.88 ± 0.95 (−8.05 to 7.68)	*14.13 ± 3.52 (13.58–14.67)*	**< 0.001**
Ap	0.41 ± 0.86 (−0.24 to 0.58)	−2.57 ± 0.83 (−2.73 to 2.41)	*2.98 ± 1.26 (2.73–3.23)*	**< 0.001**
Bp	5.36 ± 2.31 (4.91–5.82)	−2.49 ± 1.09 (−2.71 to 2.28)	*7.85 ± 2.62 (7.33–8.37)*	**< 0.001**
D	5.38 ± 2.42 (4.89–5.87) *n*=95	−8.58 ± 1.41 (−8.74 to 8.43) *n*=59	*13.99 ± 2.76 (13.27–14.71) n*=59	–
TVL	9.32 ± 1.53 (9.01–9.62)	8.43 ± 0.68 (8.29–8.56)	*0.89 ± 2.30 (0.59–1.19)*	**< 0.001**
Gh	4.97 ± 0.31 (4.91–5.03)	4.93 ± 0.27 (4.88–4.98)	*0.04 ± 0.24 (0.01–0.09)*	0.103
Pb	3.06 ± 0.63 (2.94–3.19)	3.09 ± 0.61 (2.96–3.21)	*0.02 ± 0.24 (0.01–0.29)*	0.417

Data are listed as mean ± standard deviation with 95% CI in parentheses

Bolded numbers have a *p* value of < 0.05, representing statistical significance

Aa anterior wall 3 cm from hymen, *Ap* posterior wall 3 cm from hymen, *Ba*, anterior wall, most dependent part (cm), *Bp* posterior wall, most dependent part (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)

[a] Paired *t* test

no control arm. Also, there is limited available data about this mesh system, which makes it hard to draw conclusions about its efficacy. The 1-year evaluation period may also not be long enough to draw substantial conclusions regarding the long-term cure rates and complications. A regular annual follow-up is planned in the upcoming years.

Last, although the use of mesh in POP repair is prohibited in some countries, it is well accepted in others, such as Taiwan and other oceanic countries [12]. We believe that this therapeutic option should be considered as it is relatively safe and remains effective in the long term [7] and therefore this study, although less relevant for some, still carries some importance.

Table 3 Urodynamics, UDI-6, IIQ-7, POPDI-6 and PISQ-12 scores pre- and post-surgery, $n = 101$

	Pre-operative	Post-operative 6–12 months	*p* value
Condition			
USI, overall	46[a]	17 (7, persistent; 10, de novo)	**< 0.001***
Occult	27		
Overt	19		
USI (with MUS)	42	4 (9.5%)[b]	**< 0.001***
USI (without MUS)	4	3 (67.7%)[c]	0.285*
No USI	55	45 (81.8%) (10, de novo USI)	**0.001***
DO + DOI	3	2	0.651*
UMI +	7	3	0.186*
BOO	40	1	**< 0.00**1*
DU	4	3	0.249*
Parameter			
Qmax (m/s)	15.7 ± 8.4 (14.1–17.4)	18.2 ± 8.0 (16.6–19.8)	**0.009****
Res (ml)	118.9 ± 130.3 (93.1–144.6)	42.2 ± 44.9 (33.3–51.0)	**< 0.001****
CC (ml)	409.6 ± 135.6 (382.8–436.4)	380.0 ± 137.4 (352.9–407.1)	**0.018****
MUCP (cmH_2O)	64.5 ± 25.4 (59.5–69.5)	52.8 ± 20.4 (48.8–56.8)	**< 0.001****
FUL (cm)	23.7 ± 7.4 (22.2–25.1)	21.3 ± 6.3 (20.0–22.5)	**0.006****
Dmax (cmH_2O)	22.6 ± 13.4 (20.0–25.3)	14.7 ± 8.1 (13.1–16.3)	**< 0.001****
Questionnaire			
UDI-6	9.18 ± 3.54 (8.48–9.88)	7.54 ± 2.47 (7.05–8.03)	**< 0.001****
Difference in change		1.63 ± 1.20 (1.00–2.27)	
IIQ-7	9.75 ± 5.18 (8.73–10.78)	5.51 ± 2.80 (4.96–6.07)	**< 0.001****
Difference in change		4.24 ± 1.11 (3.23–5.25)	
POPDI-6	9.74 ± 4.26 (8.90–10.58)	4.55 ± 2.61 (4.03–5.07)	**< 0.001****
Difference in change		5.19 ± 1.36 (4.33–6.05)	
CRADI-8	8.32 ± 2.88 (7.75–8.89)	6.72 ± 2.21 (6.29–7.16)	**< 0.001****
Difference in change		1.59 ± 1.12 (0.98–2.21)	
PISQ-12 ($n = 32$)	27.35 ± 7.37 (23.90–30.80)	32.50 ± 7.97 (28.77–36.23)	**0.001****
Difference in change		5.15 ± 2.16 (2.27–8.03)	

Data are listed as mean ± standard deviation with 95% CI in parentheses, number with percentage within parentheses

Bolded numbers have a *p* value of < 0.05, representing statistical significance

Qmax maximum urinary flow, *Res* postvoid residual urine, *CC* cystometric capacity, *MUCP* maximum urethral closure pressure, *FUL* functional urethral length, *Dmax* detrusor pressure at maximum flow, *USI* urodynamic stress incontinence, *MUS* mid-urethral sling, *DO* detrusor overactivity, *DOI* detrusor overactivity incontinence, *UMI* urodynamic mixed incontinence, *BOO* bladder outlet obstruction, *DU* detrusor underactivity, *UDI-6* Urinary Distress Inventory, *IIQ-7* Incontinence Impact Questionnaire, *POPDI-6* Pelvic Organ Prolapse Distress Inventory, *CRADI-8* Colorectal-Anal Distress Inventory, *PISQ-12* Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire

*McNemar test

**Paired *t* test

[a]7, UMI included

[b]2, have UMI pre-operatively

[c]1, UMI pre-operatively

Conclusion

In conclusion, the Calistar-S system is a safe and efficient method for treating POP. In a 1-year follow-up period, we observed a good anatomical outcome and subjective relief with a modest complication rate. LUTS have also been positively affected by the high success rate. Additional studies are needed to establish the long-term efficacy of this system.

Authors' Contributions T.-S. Lo: project development, management data analysis, manuscript editing; E. Rom: manuscript writing; F. Harun: manuscript editing; L.-S. Jhang: data analysis; W.-C. Hsieh: data collection; Y.-H. Lin: data analysis.

Declarations

Conflicts of Interest None.

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