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ORIGINAL ARTICLE

Anterior-apical single-incision mesh surgery (uphold): 1-year outcomes on lower urinary tract symptoms, anatomy and ultrasonography

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Abstract

Introduction and hypothesis Our primary objective is to determine the presence of SUI at 6–12 months after surgery. The secondary objective is to determine the objective and subjective outcomes of POP.

Methods A retrospective study conducted between February 2015 and July 2016 at Chang Gung Memorial Hospital. The subjects had had symptomatic anterior or apical prolapse with stage III or IV and undergone pelvic reconstructive surgery using Uphold™ LITE. Patients completed a 3-day voiding diary, urodynamic study, real-time ultrasonography and validated quality-of-life questionnaires at baseline and 12-month follow-up. Primary outcome was the absence of USI. Secondary outcomes included the *objective cure rate of POP*, ≤ stage 1 at the anterior/apical vaginal wall, and the *subjective cure rate*, negative feedback to POPDI-6.

Results Ninety-five women were eligible. Six were excluded because of incomplete data. The postoperative de novo USI and SUI were 22.7 and 19.7%, respectively. There was significant improvement of USI in patients who had MUS insertion (93.8%) and bladder outlet obstruction (96.7%). The objective and subjective cure rate for prolapse was 95.5 and 94.3%, respectively. POP-Q measurements pre- and postoperatively were significantly improved at all points except for Gh and Pb. There was a significant difference in the distance between the bladder neck to the distal end of the mesh during straining both at both the postoperative 3rd month and 1 year.

Conclusions Uphold™ mesh has a 20% incidence of de novo USI with acceptable objective and subjective cure rates at 1 year postoperatively. The de novo USI rate was high but not bothersome enough to require surgery.

Keywords Anterior apical mesh · Outcome · Ultrasonography

Introduction

The approach to the surgical management of pelvic organ prolapse (POP) has undergone several paradigm shifts in the last few decades [1]. Numerous surgical procedures have been described, both vaginal and abdominal, to provide the best surgical repair for POP. Among the common procedures for the correction of apical prolapse, sacrospinous ligament fixation (SSF) has been well described. However, the efficacy of unilateral SSF in preventing and treating apical prolapse

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ranged between 78 and 96% [2], with documented recurrence risk of anterior prolapse [1]. In response, this has prompted surgeons to use grafts in pelvic reconstructive surgery. Lo et al. reported long-term favorable and sustainable anatomical and subjective outcomes in advanced POP, comparing SSF with non-absorbable anterior vaginal mesh and anterior colporrhaphy [2]. A combined apical/anterior mesh procedure in advanced POP showed equally promising outcomes, but with extensive surgery comes the risk of developing de novo stress urinary incontinence (SUI) especially involving paravesical dissection [3–5]. Since the warning issued by FDA on its safety issue, these kits has been limited to specially trained surgeons. The Uphold™ (Boston Scientific) Lite vaginal mesh system is designed for apical/anterior support with proximal mesh placement on bilateral sacrospinous ligaments utilizing the Capio Slim™ (Boston Scientific) suture capturing device with no distal anchorage. Few studies have described the morphology of mesh regarding its anchorage [4, 6]. With the smaller mesh footprint and plausibly less paravesical dissection using the Capio Slim™, we studied its surgical outcomes, including the morphology, and whether this mesh system with no caudal fixation and plausibly less paravesical dissection would predispose patients to urodynamic stress incontinence (USI). Our primary objective was to determine the presence of USI 6–12 months after surgery. The secondary objective was to determine the objective and subjective outcomes of POP using the Uphold™ System.

Materials and methods

The institutional review board approved this retrospective study (IRB no. 201800076B0). The study period was between February 2015 and December 2016 in three tertiary centers: Keelung, Taipei and Linkou Chang Gung Memorial Hospitals. All screened and eligible patients who attended the urogynecology clinic during the study period with stage III or IV symptomatic anterior or apical prolapse according to the Pelvic Organ Prolapse Quantification System (POP-Q)/International Continence Society (ICS) [7] underwent pelvic reconstructive surgery using the Uphold™ LITE Vaginal Support System (Boston Scientific).

We excluded patients who had previous POP surgery with mesh augmentation, previous anti-incontinence procedures and radical pelvic surgery. SUI was diagnosed based on clinical symptoms and confirmed with a cough stress test and multichannel urodynamic evaluation, which was performed in semi-lithotomy position, and prolapse was reduced with a ring pessary. USI was defined as an involuntary urinary leakage with increased in intraabdominal pressure in the absence of detrusor contraction during filling cystometry [7]. Patients who only had SUI when the prolapse had been repositioned were considered to have occult SUI [7].

Preoperative baseline assessments included detailed clinical history and physical examination, including a pelvic examination, cough stress test, baseline urine analysis, 1-h pad test, 3-day voiding diary and multichannel urodynamic evaluation, which was done for all participants with or without complaints of urine leakage in order to diagnose occult SUI. POP staging and sonography were performed by the senior author, and POP staging was recorded according to the POP-Q system [7]. All patients completed the validated quality-of-life questionnaires, i.e., Incontinence Impact Questionnaire-7 (IIQ-7) [8], Urogenital Distress Inventory 6 (UDI-6) [9], Pelvic Organ Prolapse Distress Inventory 6 (POPDI-6) [9], Colorectal-Anal Distress Inventory (CRADI-8) [3] and the Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire (PISQ-12) [10] at baseline and at 12-month follow-up. Validated Chinese versions were used for questionnaires [11]. All conditions were defined according to the standards of the ICS [7].

All participants were counseled regarding the potential benefits and possible intra- and postoperative complications, mesh-related complications, possibility of needing additional procedures and possible recurrence risk of prolapse and SUI. The decision concerning concurrent TOT was based on patient's preference after the risks and benefits had been explained. Informed consent was obtained from all patients prior to participation in this study.

Operative procedure

All surgical procedures were performed by the same author (T.S.L.) in the following order: vaginal hysterectomy (VTH), Uphold™ LITE Vaginal Support System with the Capio SLIM™ Suture Capturing Device (Boston Scientific, Marlborough, MA, USA) and posterior colporrhaphy. For patients who had USI and consented to anti-incontinence surgery, a concomitant mid-urethral sling (MUS) was performed.

The surgical technique involved dissecting the paravesical fossa reaching the sacrospinous ligaments where the proximal apical strips were inserted using the Capio SLIM™ device. The vaginal apex was identified, and a 2/0 polyglactin absorbable suture was placed to fix the mid-portion of the proximal end of the mesh. The distal end of the mesh was transfixed to the paravaginal fascia and urethrovesical junction to cover the cystocele using three to five interrupted Vicryl 1/0 sutures. Posterior colpo-perineorraphy was performed if there was posterior compartment prolapse.

All patients had cystoscopy to evaluate the integrity of the lower urinary tract at the end of the procedures. Prophylactic intravenous antibiotics, cefazolin 500 mg,

were given for every patient prior to the surgery and every 6 h for 1 day. Vaginal packing was done with gauze soaked with povidone-iodine and left in situ for 24 h. A Foley catheter was inserted during the operation and removed following the removal of vaginal packing. After the removal of the Foley catheter, patients were encouraged to urinate freely and discharged home if the residual volume was consistently < 20% of the voided volume. The bladder was scanned (BVI 3000; Diagnostic Ultrasound Corp., Bothell, WA, USA) for post-void residual measurement after Foley catheter removal. Sterile intermittent catheterization was performed when the post-void residual urine volume exceeded 150 ml.

Outpatient follow-up visits were scheduled at 1 week, 1 month, 3 months, 6 months, 12 months and 1 year postoperatively based on our institutional protocol. During the follow-up visit, patients were assessed subjectively and objectively with pelvic examination and POP-Q evaluation performed. UDs were scheduled at 1 year postoperatively. However, for those patients who complained of SUI after surgery, we offered UDs and the pad test earlier, between 6 and 12 months postoperatively. Quality-of-life questionnaires were also done at 1 year postoperatively. Telephone follow-ups by a credentialed nurse were made for patients unable to participate in clinical follow-ups. Patients with USI after surgery were offered the options of conservative treatment and surgery.

Outcome measures

The primary outcome measures were the presence of de novo or persistent USI in urodynamic studies or 1-h pad test at 6–12 months after surgery. Subjective outcomes were based on the UDI-6 and IIQ-7 questionnaires at 1 year postoperatively.

The secondary outcome measures were the *objective cure rate of POP*, defined as ≤ stage 1 prolapse at the anterior or apical vaginal wall and absence of voiding dysfunction at 1 year after the surgery. The *subjective cure rate* was based on the patient's negative feedback to questions 2 (no or mild heaviness) and 3 (no or mild abdominal organ-falling sensation) in the Pelvic Organ Prolapse Distress Inventory 6 (POPDI-6) questionnaire at 1 year postoperatively [8], and the changes in quality of life were assessed by the self-administered UDI-6, IIQ-7, POPDI-6, PISQ-12 and CRADI-8 questionnaires and voiding dysfunction at 6–12 months after surgery. The comparison of two-dimensional introital ultrasonography at the 1st and 3rd months and 1 year after surgery were also measured as the secondary outcomes. Two-dimensional introital ultrasonography was performed with the patient in a semi-supine position (Fig. 1) to evaluate the topographic and anatomical measurement of the implanted mesh. A 3.5-MHz curved linear array transducer (Philips HD11 XE; Philips Healthcare, Eindhoven, The Netherlands) was positioned next to the vaginal introitus to studying the structure of the implanted mesh in the sagittal and transverse planes. Both the thickness plus length of the mesh (TVM-T) and thickness of the vaginal mucosa (Mucosa-T) between the outer vaginal wall and mesh margin were measured with the patient at rest (Fig. 1). The distance from the bladder neck to the distal end of the mesh was measured both at rest (TVM-BN-rest) and during maximum Valsalva (TVM-BN-strain).

Statistical analysis

Descriptive statistics were used for the demographics and perioperative data. Paired-samples t-test and either the chi-square or Fisher exact test were applied for comparison of pre- and postoperative continuous and categorical data, respectively. Values of $p < 0.05$ were considered statistically significant for all comparisons. All statistical methods were performed using the commercial software SPSS, version 17.

Results

Ninety-five women were eligible. Six patients were excluded from the study because of incomplete data (Fig. 2). A telephone interview was made to ensure the safety of these patients after surgery. However, for various logistic reasons patients were not able to come for follow-up. A total of 89 were included in the final analysis.

Patients' demographic data are shown in Table 1. Mean age was 64.7 ± 9.2 years, and the majority of patients (94.7%) were post-menopausal. Median patient follow-up was 18.3 ± 4.8 months. The majority had concomitant vaginal hysterectomy (92%), but only 16% had concomitant trans-obturator tape. The outcomes in Table 1 show a case of bladder injury (1%). The postoperative de novo USI and SUI were 22.7% (15/66, $p < 0.001$; objective outcome) and 19.7% (13/66, $p < 0.001$; subjective outcome), respectively. The objective and subjective cure rates for prolapse were 95.5 and 94.3%, respectively. POP-Q measurements at pre- and postoperative follow-ups at 1 year showed significant improvements for Aa, Ba, C, Ap and Bp and significant shortening for TVL (Table 2). A bar chart shows the POP-Q staging preoperatively and at the 1-year postoperative follow-up after anterior-apical single-incision mesh surgery at the overall

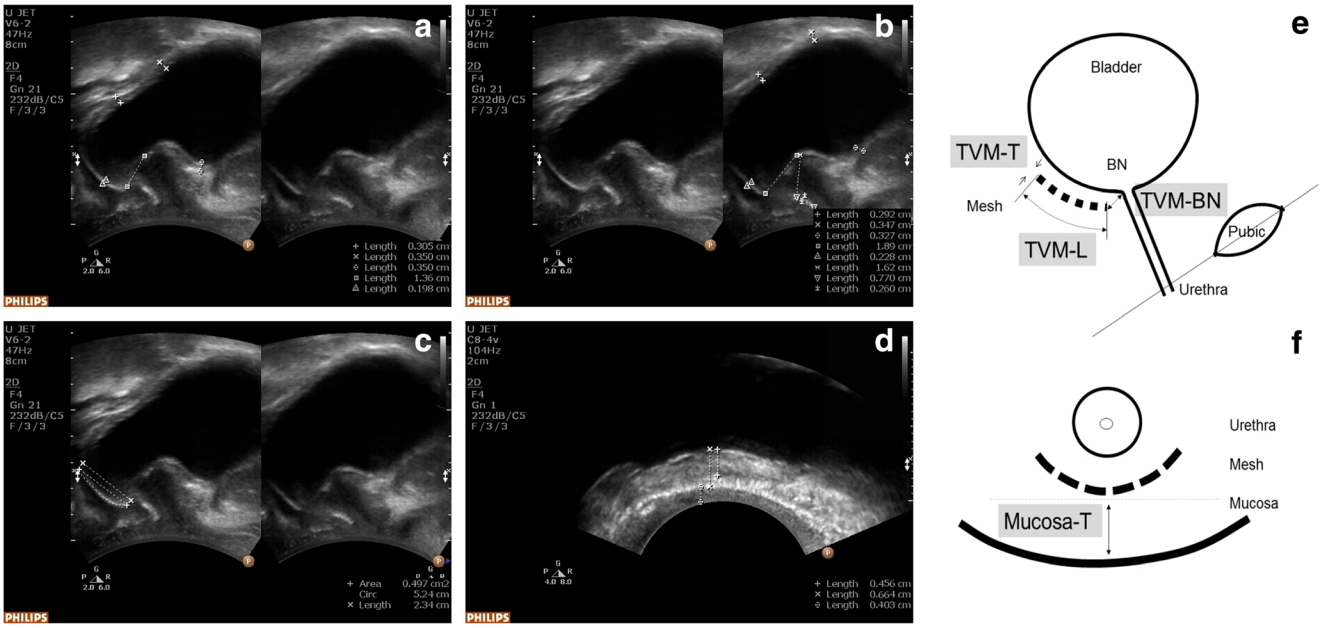


Fig. 1 Introital ultrasound and measuring methods. (**a**) Measurements for Uphold mesh and in relation to the bladder neck at rest. (**b**) Measurements for Uphold mesh in relation to the bladder neck during strain. (**c**) Length of the Uphold mesh. (**d**) Thickness of the mucosa. (**d**) Diagram showing the measuring method for the mesh length, thickness and distance between the bladder neck and mesh. (**e**) Diagram showing the measuring method for the mucosal thickness. BN, bladder neck; TVM-BN-rest, distance from the BN to the distal end the mesh at rest; TVM-BN-strain, distance from the BN to the distal end the mesh during strain; TVM-L, length of the mesh; TVM-T, thickness of the mesh; Mucosa-T, thickness of the vaginal mucosa

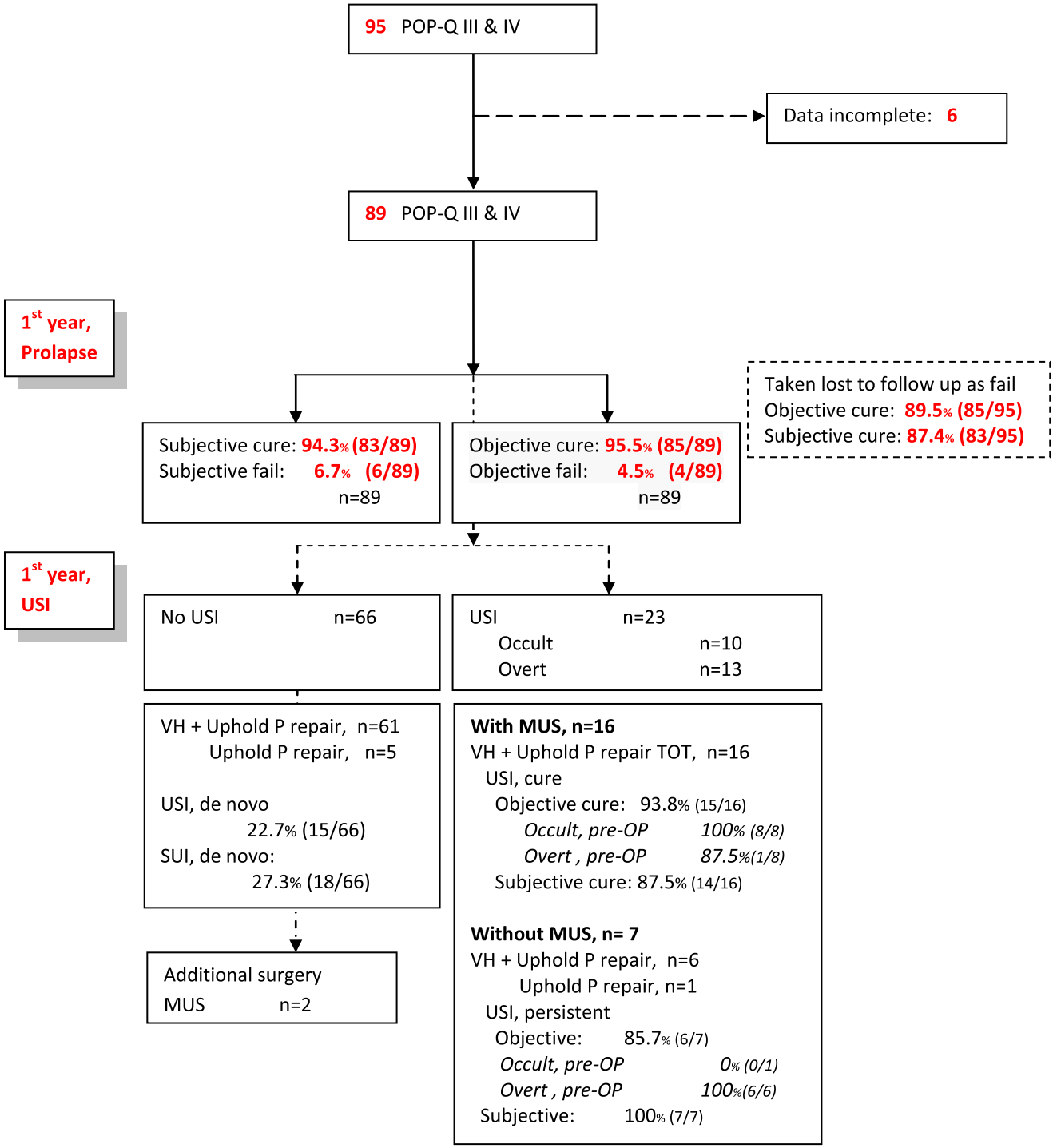
and specific compartments, namely anterior, apical and posterior. The recurrence rates for individual compartments at 1 year were 1.1% (apex) to 2.2% (anterior and posterior).

Table 3 shows urodynamic data at baseline versus postoperatively at 6–12 months. All had UDs at 1 year postoperatively, except ten that were performed before 1 year. There was a significant improvement of USI in patients who had MUS insertion (93.8%, 15/16, $p = 0.002$) and bladder outlet obstruction (96.7%, 29/30, $p < 0.001$). On the other hand, for patients who had USI preoperatively and no concurrent MUS, six of seven (85.7%, $p = 0.733$) continued to have USI postoperatively. Twenty-two patients presenting with USI preferred conservative treatment including Kegel (all) and extracorporeal magnetic energy stimulation (6 patients). For the urodynamic parameters, there were significant improvements in residual volume, MUCP, FUL and Dmax.

Topography and anatomical measurements of the mesh by introital ultrasonography for 80 patients are shown in Table 4. There was a significant difference in the distance between the bladder neck (BN) and the distal end of the mesh during straining (TVM-BN-strain) at both the 3rd postoperative month and 1 year (Table 4, Video 1). Concerning the length and thickness of the mesh (TVM-T), a significant difference at 1 year postoperatively compared with 3 months after surgery was revealed. Table 3 compares pre- and 1-year post-surgery of UDI-6, IIQ-7, POPDI-6, (CRADI-8) and PISQ-12. There was significant improvement of the scores for all the questionnaires (Table 3).

Discussion

In our study a quarter of the patients had POP associated with USI (23/89), with 56% (13/23) overt and 43% (10/23) occult (Table 3). The rate of USI was high between postoperative 6 to 12 months, for both persistent (85.7%, without concurrent MUS) and de novo USI (22.7% 15/66), which coincides with recent studies using single-incision mesh systems [5, 12]. True rate of de novo USI is 22.7% (15/66), and the persistence USI after MUS is 6.3% (1/16). Previous studies involving opening of the paravesical space in prolapse surgery had higher rates of de novo SUI [4, 5, 13], while concurrent vaginal hysterectomy in prolapse surgery was not a risk factor for de novo USI [3]. We believe that paravesical dissection during surgery has a negative impact on anterior support and thus increases the rate of de novo USI. The observed reduction of MUCP ($P < 0.001$) strongly supports our theory. Other factors besides surgery involving the dissection of the paravesical space causing de novo and persistent



Objective cure: POP-Q < stage 1 (all compartment) & absence of voiding dysfunction
Subjective cure by patient feedback using questions 2 and 3 of POPDI-6

Fig. 2 Flow chart

SUI were age > 66 years, DM, low MUCP and FUL [3, 14]. Like previous studies, most cases of postoperative de novo USI were not bothersome and rarely needed surgical intervention [5, 12]. However, in patients who may require and opt for concurrent MUS, proper counseling should be done concerning the significant risk of voiding

Table 1 Baseline patients demographics and surgical outcomes, n=95

Mean age (year)	64.7 ± 9.2
Median parity (range)	3.0 (1-8)
Mean BMI (kg/m^2)	26.2 ± 3.1
Postmenopausal	90
Prior pelvic surgery	5
LH	1
TAH	4
Mean operating time (min)	68.9 ± 15.0
Mean intraoperative blood loss (ml)	85.5 ± 89.7
Mean hemoglobin difference (g/dl)	1.17 ± 0.76
Mean hospital stay (days)	3.24 ± 0.53
Median period of follow-up (months)	18.3 ± 4.8
Concurrent surgery (n)	
VH	88
TOT	16
Posterior coloporraphy	95
Complications,	
Bladder injury	1*
Mesh exposure, vagina (n, %)	0
Objective cure on prolapse at 1 year (n, %)	85/89 (95.5%)
Anterior	87/89 (97.7%)
Apex	88/89 (98.9%)
Posterior	85/89 (95.5%)
Subjective cure on prolapse at 1 year (n, %)	83/89 (94.3%)

Data listed as either mean ± standard deviation or median with range in parentheses

BMI, body mass index; TAH, total abdominal hysterectomy; LH, Laparoscopy hysterectomy. TOT, trans-obturator tape

*Injury at dissection; Repair immediate; Followed by Uphold surgery; Foley maintained for 3 day; Uneventful after surgery & up to date

dysfunction postoperatively. The overall postoperative voiding dysfunction after pelvic reconstructive surgery with and without MUS for advanced prolapse was 7.8 and 2.3%, respectively, based on our previous study [15]. With this rate, it is reasonable to have 70% (16/23) opt for concurrent MUS after thorough counseling. On the other hand, patients who had postoperative USI were managed conservatively and surgically, and this was included in the preoperative counseling. Twenty-two patients were observed to have postoperative USI under strict UDS criteria. The decision for secondary MUS was dependent on the severity and bio-behavioral model of clinical symptoms and was individualized. Our data on secondary MUS were short term and may differ at a longer follow-up period. Although there was about 22% de novo USI and 27.3% complained of SUI, subjective outcomes were significant as seen in the answers to the UDI-6 and II-Q questionnaires. Uphold was also not associated with an increase in postoperative DO. As seen in a previous study on predictors of postoperative DO after pelvic reconstructive surgery, only age ≧ 66 years, neurological factors like CVA and Parkinson's disease, preoperative MUCP ≥ 60cmH_2O, MFR < 15 ml, Dmax ≥ 20cmH_2O and PVR ≥ 200 ml were found to be independent risk factors [16].

At 1 year postoperatively, the Uphold mesh had an objective and subjective outcome of 95.5 and 94.3%, respectively, which is comparable to the results of a previous study by Manhan et al. [17] and other anterior-apical single-incision mesh systems [4, 5].

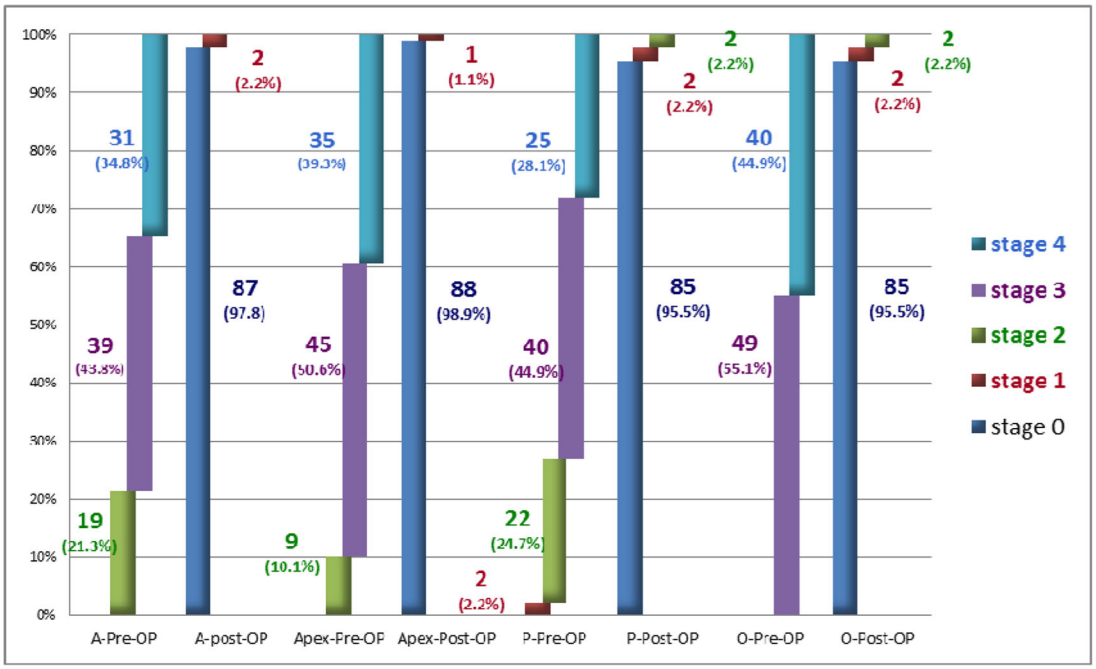
Anatomical outcomes in POP showed significant improvements in both the specific and overall compartments (Table 2). Rivaux et al. reported similar objective outcomes (93% success rate) in their longitudinal case series of 59 patients [18]. In another intermediate cohort study, the reported success was 93% [12]. There was no recurrence requiring further surgery at 1-year follow-up. Similar results were seen for subjective outcomes measured by the same questionnaires. In this study, we dealt not only with prolapse outcomes but also with USI. We also explored the mesh morphology, which is currently ignored by most authors. The authors postulated that the absence of a distal anchorage to obtain a minimum three-point plane would be inadequate for support. However, the outcome negated our hypothesis. The objective outcome was similar to a four-point plane mesh system with a pair of distal anchorages [5]. Interestingly, there was no increase in anterior compartment recurrence. Possible contributing factors were the surgical technique to transfix the edge of the mesh to the vaginal fascia to avoid straining for the first 3–6 months postoperatively to allow complete healing with fibrosis and provide strong and durable anterior support. In addition, postoperative supervised pelvic floor exercise with a dedicated physiotherapist ensured good pelvic muscle tone, even though it might not be beneficial to preserving surgical outcomes.

Aside from a bladder injury, there were no significant complications. To date, there has been no mesh erosion, probably because of the lightweight macroporous inert mesh and good surgical technique. Uphold™ has no anterior arm or mesh over the apex of the vaginal vault, decreasing the risk of mesh erosion at the apex associated with concurrent hysterectomy. Manhan et al. reported a mesh erosion rate of 2.6% with Uphold™ mesh, and 2/3 cases had a concurrent hysterectomy [17]. Two other studies reported around 3.5% mesh exposure [12] and 3.4% reoperation for mesh-related complications [12]. Currently, there has been no reported bladder injury using Uphold™ in the literature; a study on lightweight polypropylene mesh in POP had 2% perioperative complications, including urinary bladder injury and severe blood loss [19].

Our data suggested that, concerning Uphold's™ length, the mesh elongated over time. This could be explained by the direct pressure effect of the cystocele on the mesh together with the pulling effect from the posterior arms that

Table 2 Pelvic organ prolapse quantification measurement at pre-operative and post-operative follow-up. n=89

	Pre-	Post-OP 1 year	Difference between pre-OP and post-OP 1st *year*	P value[a]
Aa	1.33 ± 1.33 (1.08-1.57)	-2.69 ± 0.22 (-2.71—2.52)	4.02 ± 1.32 (-4.2—3.75)	<0.001
Ba	7.73 ± 2.88 (7.39-8.14)	-2.36 ± 0.32 (-2.51—2.22)	10.07 ± 2.85 (9.07-11.01)	<0.001
C	7.52 ± 2.04 (7.11-7.93)	-8.43 ± 2.03 (-9.83—9.02)	15.95 ± 3.99 (16.34-1657)	<0.001
Ap	0.21 ± 1.14 (-0.12-0.50)	-2.69 ± 0.58 (-2.79—2.40)	2.90 ± 1.12 (2.16-3.11)	<0.001
Bp	6.15 ± 2.54 (5.64-6.65)	-2.79 ± 0.48 (-3.09—2.60)	8.94 ± 3.80 (8.45-9.65	<0.001
D	5.31 ± 2.41 (4.82-5.81) n=84	-9.00 ± 1.41 n=2		
TVL	10.74 ± 1.65 (8.41-11.07)	9.41 ± 2.11 (7.99-9.83)	-1.33 ± 1.56 (-0.86—1.79)	<0.001
Gh	5.15 ± 0.83 (4.64-5.65)	4.86 ± 0.36 (4.79-4.93)	-0.29 ± 0.69 (-2.22-0.79)	0.264
Pb	2.46 ±0.69 (2.12-2.70)	2.40 ± 0.52 (2.19-2.60)	0.06 ± 0.27 (0.02-0.27)	0.282



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

A-Pre-OP, anterior compartment at preoperative POP-Q stage; A-Post-OP, anterior compartment at postoperative POP-Q stage; Apex-Pre-OP, apical compartment at preoperative POP-Q stage; Apex-Post-OP, apical compartment at postoperative POP-Q stage; P-Pre-OP, posterior compartment at preoperative POP-Q stage; P-Post-OP 5 posterior compartment at postoperative POP-Q stage; O-Pre-OP, overall at pre-operative POP-Q stage; O-Post-OP, overall at post-operative

Objective cure rate (by POPQ ≤ stage 1); (anterior = 97.7%; Apical = 98.9%; Posterior = 95.5%; Overall = 95.5%)

stretched the mesh during healing prior to complete maturation of fibrosis. In addition to the two-arm anchorage, at least three points of the mesh were sutured to the vaginal mucosa for support. Without these additional fixations on both the distal and proximal part of the mesh, the mesh might be shortened [20, 21]. However, these additional points of fixation still need further study. The same elongation was observed with other anterior-apical single-incision mesh systems [4, 5]. Uphold™ provides good apical support, demonstrated by point C at 1 year. The posterior arms of Uphold™consist of mesh and are reinforced with a prolene suture covered by a plastic sheath facilitating the pulling adjustment. This stiff suture line prevents folding of the mesh arm while adjusting in a tension-free manner. The Capio SLIM™ device is used because of its posterior arm fixation through palpation, requiring minimal dissection of the paravaginal space, hence reducing the blood loss and complications. The gradual thickening of the mesh over a year may be a result of the complexity of the fibrosis, tissues and mesh.

Table 3 Urodynamic data at 6-12 months, and UDI-6, IIQ-7, POPDI-6 and PISQ-12 questioner score at 1 year, (baseline vs. post-operative) n=89

Condition	Pre-operative		Post-operative 6-12 months		*p* value
USI, overall	23		22 (7, persistent; 15, de novo)		0.863
Occult	10				
Overt	13				
USI (with MUS)	16		1 (6.3%)		0.002*
USI (without MUS)	7		6 (85.7%)		0.733
No USI	66		51 (77.3%) (15, de novo USI)		<0.001
DO/DOI	2 / 4		0 / 1		0.059*
Mixed incontinence	5		4		0.500*
BOO	30		1		<0.001*
DetU	7		3		0.330*
Parameter, Urodynamics	Pre-operative		Post-operative 6-12 months		*p* value**
Qmax	15.3 ± 7.5	(13.8-16.8)	17.1 ± 7.9	(15.7-18.7)	.018
Res	79.7 ± 125.7	(54.7-104.8)	39.6 ± 75.1	(24.6-54.6)	.001
CC	396.3 ±119.8	(372.4-420.2)	373.4 ± 98.9	(353.7-393.1)	.060
MUCP	66.6 ± 24.1	(61.8-71.4)	54.4 ± 20.0	(50.4-58.4)	<0.001
FUL	23.5 ± 6.1	(22.3-24.8)	21.2 ± 5.7	(20.0-22.3)	.002
Dmax	26.9 ± 22.4	(22.4-31.4)	16.5 ± 12.3	(14.0-18.9)	<0.001
Parameter, Questionnaire	Pre-operative		Post-operative 6-12 months		*p* value**
UDI-6	12.6 ± 3.3	(10.8-14.3)	10.5 ± 2.7	(10.0-12.1)	<0.001
Difference, [% change]			2.0 ± 1.6	(1.2-2.9)	
IIQ-7	11.2 ± 3.5	(9.5-12.9)	6.6 ± 2.1	(5.4-7.8)	<0.001
Difference, [% change]			4.7 ± 1.6	(3.8-5.6)	
POPDI-6	14.3 ± 5.0	(11.8-17.1)	11.1 ± 2.2	(9.8-12.5)	<0.001
Difference, [% change]			3.2 ± 1.6	(2.5-4.0)	
CRADI-8	17.7 ± 3.9	(15.8-19.9)	14.3 ± 2.3	(12.8-15.9)	<0.001
Difference, [% change]			3.4 ± 1.3	(2.7-4.2)	
PISQ-12	24.1 ± 5.9	(21.0-27.4)	28.9 ± 3.3	(27.2-3.01)	.002
Difference, [% change]			4.8 ± 1.3	(3.9-5.5)	

Data listed as mean ± standard deviation with 95% CI in parenthesis or 100 percentile within parentheses

Qmax, maximum urinary flow (m/s); Res, postvoid residual urine (ml); CC1D, first desire to void (ml); CC, cystometric capacity (ml); MUCP, maximum urethral closure pressure (cmH_2O); FUL, functional urethral length (cm); Dmax, detrusor pressure at maximum flow (cmH2O); USI, urodynamics stress incontinence; DO, detrusor overactivity; BOO, bladder outlet obstruction; DetU, detrusor underactivity

UDI-6, Urinary Distress Inventory; IIQ-7, Incontinence Impact Questionnaire; POPDI-6, Pelvic Organ Prolapse Distress Inventory 6; CRADI-8, Colorectal-Anal Distress Inventory; PISQ-12, Pelvic Organ Prolapse/ Urinary Incontinence Sexual Questionnaire;

* Fisher exact test.** Paired t test

The distance of the mesh from the bladder neck did not change over time at rest but increased during straining. At rest, the dorsal movement of the mesh edge was not significant probably because the mesh was stitched to the vaginal fascia, holding it in place for fibrosis to set in. During straining, the significant dorsal movement of the edge of the mesh suggests that the anchorage by fibrosis from the stitches was not strong enough to counter the increase in abdominal pressure during straining, hence exposing a small gap in between them (Video 1). Long-term follow-up with particular attention to this mechanism would allow us to identify any possibility of developing cystocoele through this gap. The apex is well supported by fixating the mesh via tapes to the sacrospinous ligament, and the smaller mesh acts to provide suspended reinforcement to the anterior compartment for prevention of anterior recurrences [1].

The strength of our study is the standardized evaluation protocol using urodynamic study and validated questionnaires, mimicking a prospective case-control study. However, the limitation includes a retrospective, single-arm study, and a 1-year follow-up period may not be long enough to draw substantial conclusions.

Conclusion

In conclusion, the Uphold™ mesh has > 20% incidence of de novo USI and acceptable objective and subjective cure rates at 1 year postoperatively. The de novo USI rate was high in patients with uphold but was not bothersome enough to require surgical intervention. The POP-Q findings for

Table 4 Topography and anatomical measurements of the mesh, n=80 (mean±SD), by introital ultrasonography

Parameter (mm)	First month	Third months	One year	*p* value
TVM-BN-rest	10.78±0.58 (10.47-11.10)	10.84±0.43 (10.55-11.12)		0.366
			10.91±0.52 (10.61-11.22)	0.077
TVM-BN-strain	14.28±0.80 (13.09-14.64)	14.68±0.61 (14.56-14.81)		<0.001
			15.81±0.53 (15.51-16.12)	<0.001
TVM-L	30.06 ± 5.54 (28.95-31.16)	31.05 ± 5.29 (29.99-32.11)		0.142
			32.68±5.31 (31.62-33.73)	<0.001
TVM-T	2.19 ± 1.39 (1.81-2.47)	2.48 ± 1.31 (2.22-2.74)		0.125
			2.84±1.43 (2.55-3.12)	0.002
Mucosa-T	5.24 ± 4.29 (4.38-6.09)	4.95 ± 3.34 (4.28-5.61)		0.488
			4.59±3.47 (3.90-5.29)	0.162

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

BN = bladder neck; TVM-BN-rest, distance from BN to distal end the mesh at rest; TVM-BN-strain, distance from BN to distal end the mesh during strain; TVM-L, length of the mesh; TVM-T, thickness of the mesh; Mucosa-T, thickness of vagina mucosa

p value, for the comparison between third month and first year postoperatively to the first month postoperatively

lengthening of point C and the total vaginal length were supported by ultrasound, which showed an increase in mesh length over the 1-year follow-up.

Compliance with ethical standards

Conflicts of interest None

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