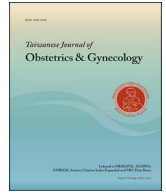




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Original Article

Evaluating the efficacy of the single-incision uphold system for pelvic organ prolapse repair

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ABSTRACT

Objective: The aim of this study was to assess the efficacy and clinical outcomes of pelvic floor reconstruction with transvaginal mesh of the Uphold™ Vaginal Support System (Boston Scientific Corporation).

Materials and methods: This retrospective study reviewed the medical records of patients with pelvic organ prolapse stage 3 or 4 who underwent pelvic reconstructive surgery with transvaginal mesh of the Uphold™ Vaginal Support System from January 2015 to March 2017. Patients who were treated with laparoscopic sacrocolpopexy, transvaginal sacrospinous ligament suspension or other mesh kits were excluded. Assessments included pre- and postoperative Pelvic Organ Prolapse Quantification (POP-Q) stage, Urogenital Distress Inventory-6 (UDI-6), Incontinence Impact Questionnaire-7 (IIQ-7), urodynamic parameters, peri- and postoperative complications and symptoms.

Results: Of the 111 enrolled women, the anatomical success rate was 97.3% after a median 18.4 months of follow-up. POP-Q parameters, UDI-6 and IIQ-7 scores, maximum urine flow rate, and post-void residual urine all significantly improved after surgery. Complications included one case (0.9%) of infected hematoma, two cases (1.8%) of mesh exposure, three cases (2.7%) of recurrent prolapse, and 12 cases (10.8%) of transient urine retention. No bladder or bowel injuries occurred during surgery.

Conclusions: Pelvic reconstructive surgery with transvaginal mesh of the Uphold™ System yielded satisfactory anatomical and urinary functional outcomes in a median 18.4 months of follow-up.

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Introduction

Pelvic organ prolapse (POP) is defined as the downward descent of the pelvic organs causing vaginal protrusion, and it is an important public health issue which affects nearly 30% of all women during their lifetime [1,2]. Several surgical methods are currently used to treat POP, either via an abdominal or vaginal route. Vaginal surgery with native tissue repair is associated with high long-term recurrence rates [3], whereas synthetic mesh for POP repair generally improves anatomical outcomes and reduces the risk of recurrent prolapse [4]. However, complications related to the use of vaginal mesh have been reported, including mesh erosion, infection, voiding dysfunction, and dyspareunia [5].

These complications may arise from the operative technique or be related to the nature of the mesh itself. Thus, there is a trend toward reducing the burden of biomaterial. In addition, instead of covering the presumed defect using a large-surface mesh, the role of apical support in POP is also gaining in importance [6]. Some studies have suggested that native tissue repair or covering the anterior vaginal tissue defect with mesh without addressing the apical defect may contribute to an unfavorable recurrence rate [6,7]. The Uphold™ Vaginal Support System (Boston Scientific Corporation) is the second generation of a prefabricated mesh kit that decreases biomaterial load to avoid mesh-related complications [6]. Surgery with this transvaginal commercial kit is performed through a single incision, and it can be used for both anterior and apical repair. We use this system for women with stage 3 or 4 POP at our hospital. The aim of this study was to assess the clinical outcomes, peri- and post-operative complications and associated morbidity.

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Materials and methods

Ethical approval was obtained from the Institutional Review Board of our hospital for retrospective data analysis. Charts were reviewed from January 2015 to November 2017. In this period at our hospital, there were 400 patients who underwent transvaginal mesh surgery for pelvic organ prolapse (uterus was preserved in 70–80% of these cases) and 67 patients who underwent laparoscopic sacrocolpopexy. We reviewed the charts of patients with Pelvic Organ Prolapse Quantification (POP-Q) stage 3 or 4 who received Uphold mesh repair. One hundred and twenty-four patients were identified from the medical records, all of whom were followed for a minimum of 12 months to a maximum of 36 months. All patients were operated on by two experienced pelvic floor surgeons (Huang KH and Chuang FC; both at a senior consultant level at our hospital). All of the patients with stage 3 or 4 POP were treated with the Uphold mesh system during the study period. Patients with stage 3 or 4 POP who were treated with laparoscopic sacrocolpopexy or transvaginal sacrospinous ligament suspension or another mesh kit were excluded from this study. Thirteen patients were excluded due to a follow-up period of less than 12 months and insufficient data. Pre- and post-operative assessments included Urogenital Distress Inventory-6 (UDI-6), Incontinence Impact Questionnaire-7 (IIQ-7), pelvic examination, POP-Q staging, multichannel urodynamic studies, 1-h pad test, and cough stress test after repositioning of the prolapsed compartment. Pre-operative POP-Q values were measured at the outpatient clinic and redone in the operation room. Post-operative POP-Q values and stages were measured at each follow-up visit at our clinic. All of the patients provided informed consent with regards to the risks of transvaginal mesh (including the FDA warning). We informed the patients planning to undergo transvaginal mesh of the possible serious complications such as bladder or rectum injury, mesh erosion, and chronic pelvic pain. Furthermore, all of the patients without postmenopausal bleeding, abnormal cervical Pap smears, previous cervical neoplasms, or uterine diseases were offered the option to preserve the uterus. The operative procedure was performed using the technique outlined by the manufacturer except for subtle differences, including performing the vaginal single incision vertically rather than horizontally. We used the vertical incision at anterior vaginal wall from the level of the bladder neck to the cervix (in uterus-sparing group), or to vaginal apex (post-hysterectomy). In uterus-sparing patients, the superior mesh edge was fixed below the bladder neck and the inferior edge was affixed to the paracervical ring. After the mesh was inserted it was fixed to the apex area, followed by fascia repair of the anterior and posterior vaginal wall. Any redundant vaginal wall was then trimmed during vaginal repair. After surgery, cystoscopy and a digital examination were routinely performed to exclude bladder and colorectal injuries, and to check the patency of bilateral ureters.

All patients received prophylactic antibiotic (intravenous cefazolin 1 g) treatment 30 min before surgery and for 2–3 days (intravenous cefazolin 1 g every 8 h) after surgery. All procedures were performed with the patients under general or regional anesthesia, depending on the anesthesiologist. The following pre- and post-operative data were recorded: urinalysis, hemoglobin 24 h before and after surgery, operative time, estimated blood loss, days with a urine indwelling catheter, days of hospitalization, and peri-operative complications. Post-operative follow-up was scheduled at 1 week, 1, 3, 6 and 12 months, and annually thereafter. Abnormal urinary symptoms included dysuria, nocturia, frequency, urgency, urgency incontinence, and stress urinary incontinence as per the 2002 International Continence Society definition [8]. Post-operative urodynamic examinations were performed about 6 months later. Mesh extrusion was confirmed by routine follow-up

pelvic examinations. Recurrence was defined as the most distal portion with a POP-Q stage of more than 2.

Continuous variables were expressed as means and standard deviations, and pre- and post-operative comparisons were made using the Student's *t* test. Changes between pre- and post-operative POP-Q values were assessed using the paired Student's *t* test. All data analyses were performed using IBM SPSS Statistics version 20 for Mac. Differences were considered statistically significant at a *p* value < 0.05.

Results

A total of 111 patients were enrolled for analysis in this study. Background demographic data including age, parity, body mass index, menopausal status, medical and surgical history are presented in Table 1. Most of the patients (96%) were menopausal, and 30 (27%) had diabetes mellitus under medical control. Eight (7.2%) patients had previously undergone hysterectomy, including transabdominal hysterectomy, supracervical hysterectomy, laparoscopy-assisted vaginal hysterectomy, or transvaginal hysterectomy. All of the 111 patients had anterior prolapse with a POP-Q stage of more than 2, 109 (98.2%) had apical prolapse with a POP-Q stage of more than 2, and 105 (94.6%) had posterior prolapse with a POP-Q stage of more than 2.

Twenty-two (19.8%) patients underwent transvaginal hysterectomy during the transvaginal mesh procedure, and 81 (73%) patients received uterus-sparing surgery. After applying the transvaginal mesh of the Uphold support system during surgery, 97 (87.4%) patients received concomitant anterior and posterior colporrhaphy, and 12 (10.8%) patients received concomitant posterior colporrhaphy. Only two (1.8%) patients received transvaginal mesh treatment without any vaginal wall repair. Seven (6.3%) patients received anti-incontinence surgery using mid-urethral sling tape (five patients with a single-incision mini-sling, one patient with retro-pubic tension-free tape, and one patient with trans-obturator tape sling) during the prolapse repair procedure. The primary post-operative outcome analysis comparing the pre- and post-operative POP-Q values is listed in Table 2.

All parameters of the POP-Q values (Aa, Ba, C, Ap, Bp, genital hiatus, perineal body and total vaginal length) were significantly improved (*p* < 0.05). The mean follow-up duration was 18.4 months (range 12–36 months). After prolapse surgery, significant improvements in incontinence-related quality of life were noted (Table 3; *p* < 0.001 for UDI-6 and IIQ-7). Ninety-one (82%) patients completed post-operative urodynamic studies during follow-up. The pre-operative and post-operative urodynamic studies are presented in Table 3. There were significant improvements in average urine flow rate, maximum urine flow rate, voided volume, and amount of residual urine (all *p* < 0.001). The post-operative values of maximum bladder capacity and maximum urethral closure pressure were significantly decreased (*p* = 0.002 and 0.049, respectively).

Table 1
Patient's demographics.

Variable	Mean ± SD or n (%)
Age (years)	68.1 ± 9.0 (43–89)
Parity	3.4 ± 1.1
BMI (kg/m ²)	25 ± 3.5
Menopause	107 (96%)
Diabetes mellitus	30 (27%)
History of hysterectomy	8 (7.2%)
Concomitant MUS	7 (6.3%)
Follow-up time (months)	18.4 ± 6 (12–36)

Data are means ± standard deviations, or n (%).
BMI body mass index; MUS mid-urethral sling.

Table 2
Preoperative and postoperative POP-Q values (n = 111).

POP-Q variables (cm)	Mean \pm SD		p value
	Preoperatively	Postoperatively	
Aa	+2.3 \pm 1.2	−2.9 \pm 0.4	<0.001*
Ba	+4.6 \pm 1.8	−2.9 \pm 0.4	<0.001*
C	+4.2 \pm 2.2	−7.1 \pm 2.8	<0.001*
Ap	+2.0 \pm 1.3	−2.9 \pm 0.4	<0.001*
Bp	+3.6 \pm 2.3	−2.9 \pm 0.4	<0.001*
gh	5.1 \pm 0.7	3.1 \pm 0.6	<0.001*
pb	2.7 \pm 1.1	3.0 \pm 0.6	0.011*
tvI	7.7 \pm 1.8	8.2 \pm 1.2	0.008*

Data are means \pm standard deviations.

gh genital hiatus, pb perineal body, tvI total vaginal length.

*p < 0.05, statistically significant.

Table 3
Comparison of the pre- and postoperative urodynamic studies (n = 91) and questionnaires.

	Preoperative	Postoperative	p
Q max (mL/s)	17 \pm 11.6	23.4 \pm 9.0	<0.001*
Q ave (mL/s)	5.6 \pm 4.1	8.4 \pm 4.4	<0.001*
VV (mL)	210 \pm 165.9	312.6 \pm 116.7	<0.001*
RU (mL)	121.7 \pm 118.3	45.2 \pm 52.4	<0.001*
First desire	154.6 \pm 87.6	137.4 \pm 72.3	0.094
Max Cap	343.3 \pm 124.8	311.2 \pm 116.7	0.002*
MUCP	55.6 \pm 21.6	51.3 \pm 19.8	0.049*
FL	2.7 \pm 0.5	2.6 \pm 0.5	0.598
UDI-6	5.8 \pm 1.5	2.4 \pm 0.5	<0.001*
IIQ-7	8.5 \pm 1.2	3.0 \pm 0.6	<0.001*

Data are means \pm standard deviations.

Q max: maximum flow rate, Q ave: average flow rate, VV: voided volume, RU: residual urine, Max Cap: maximum capacity, MUCP: maximum urethral closure pressure, FL: functional length; Urogenital Distress Inventory-6, Incontinence Impact Questionnaire-7.

*p < 0.05, statistically significant.

The peri-operative outcomes and complications are shown in Table 4. The mean operative time was 99.5 \pm 26.6 min (range 60–205 min), the mean estimated blood loss was 62.5 \pm 57.9 ml (range 5–400 ml), and the mean duration of urine indwelling catheter was 1.9 \pm 1.1 days (range 1–8 days). No bladder or bowel injuries occurred during surgery. One (0.9%) patient had pelvic hematoma complicated with an infection post-operatively, and received conservative treatment with no further invasive procedure.

The post-operative complications are shown in Table 5. We defined transient urine retention as the need for intermittent catheterization or the replacement of a urine indwelling Foley catheter due to difficult urination after surgery during hospitalization. Twelve (10.8%) patients had transient urine retention, one of whom continued catheter use after discharge. All of these 12 patients could void smoothly by themselves within 1 month after the operation. The mesh protrusion rate was 1.8% (two patients), of

Table 4
Perioperative outcomes and complications.

Variable	Mean \pm SD or n (%)
Hospital stay (days)	5.1 \pm 1.2 (3–9)
Operative time (min)	99.5 \pm 26.6 (60–205)
Blood loss (mL)	62.5 \pm 57.9 (5–400)
Duration of urine indwelling catheter (days)	1.9 \pm 1.1 (1–8)
Pelvic hematoma	1 (0.9%)
Internal bleeding	0
Bladder/bowel injury	0

Data are means \pm standard deviations, or n, or n (lower border to upper border).**Table 5**
Postoperative complications.

Variable	N (%)
Mesh extrusion/need operation	2/1 (1.8/0.9%)
Recurrent prolapse/need operation	3/3 (2.7/2.7%)
Transient urine retention	12 (10.8%)
Infected hematoma	1 (0.9%)
Buttock pain	7 (6.3%)
De novo SUI	5 (4.5%)
De novo OAB	6 (5.4%)

SUI: stress urinary incontinence, OAB: overactive bladder.

whom one was treated with vaginal estrogen cream, and the other received surgery for excision and repair. The anatomical success rate for pelvic organ prolapse repair was 97.3%. The recurrent prolapse rate was 2.7% (three patients), two of whom (with recurrent apical prolapse dominantly) received transvaginal right sacrospinous ligament suspension surgery (one with concomitant transvaginal hysterectomy), and the other (with recurrent posterior prolapse dominantly) received another transvaginal mesh procedure with a different mesh kit (Calistar, Promedon) 4 months later. The post-operative de novo stress urinary incontinence and overactive bladder rates were 4.5% and 5.4%, respectively. None of these patients had any related urinary symptoms such as incontinence or overactive bladder before surgery, and their preoperative urodynamic study Results revealed no positive findings except for bladder outlet obstruction due to pelvic organ prolapse. Two of five patients with de novo stress urinary incontinence received anti-incontinence surgery (one with a single-incision mini-sling, one with retro-pubic tension-free tape), and the remaining three received conservative treatments for their mild symptoms. Seven (6.3%) patients reported postoperative buttock pain, all of whom received oral analgesic medication and their symptoms improved after 4–6 weeks post-operatively.

Discussion

The use of synthetic mesh for transvaginal pelvic reconstruction is an important issue. Several studies have reported that the use of transvaginal mesh in pelvic organ prolapse surgery is associated with significantly lower failure rates [9,10]. Despite possible complications related to transvaginal mesh procedures (including mesh erosion, infection, dyspareunia, and voiding dysfunction), there are benefits in performing pelvic reconstructive surgery with transvaginal mesh, especially for elderly patients, since it requires a shorter operative time and can result in good medium term success rates.

Letouzey et al. investigated 115 patients with symptomatic stage II prolapse or higher (predominantly apical prolapse) treated with Uphold mesh kits. After a mean follow-up of 23 months, the anatomical success rate was 93%, the reoperation rate for mesh-related complications (including pain and mesh exposure) was 3.4%, and the erosion rate was 2.7% [11]. Altman et al. studied 207 patients with apical prolapse with or without anterior vaginal wall prolapse greater than POP-Q stage 2 who underwent repair with Uphold mesh kits with up to 1 year of follow-up, and reported an objective success rate of 94% at the apex and a serious complication rate of 4.3%. In their series, there were three cases (1.4%) of mesh erosion/exposure requiring surgical intervention during follow-up [6]. In comparison, the anatomical success rate in the present study was 97.3%, and the mesh extrusion rate was 1.8% after a median 18.4 months of follow-up. Unlike the study of Altman et al. in which patients with posterior wall prolapse or stress incontinence were excluded, more than 90% of our patients had multiple compartment prolapses (anterior, apical and posterior prolapses at

the same time), and 87.4% of all of the patients received concomitant anterior and posterior colporrhaphy after the mesh procedure. In these cases, anterior colporrhaphy and posterior colporrhaphy are performed after implantation of Uphold mesh via trimming some redundant vaginal wall followed by fascia plication with two-layer suturing. Unlike other transvaginal mesh kit with larger area, Uphold mesh can only cover approximately half of incised vaginal wall. Thus colporrhaphy by trimming some vaginal wall after apical correction by Uphold mesh can enhance the efficacy in pelvic reconstructive surgery. Our Results showed satisfactory anatomical outcomes and a low severe complication rate in short-term follow-up after pelvic reconstruction with the Uphold mesh system, in contrast to a Cochrane Review in 2013 which reported a mesh erosion rate of up to 18% [3]. This may suggest the possible benefit of the Uphold system compared with other larger sized mesh kits. Several studies have reported that decreasing mesh biomaterial load may prevent complications such as pain or mesh exposure associated with transvaginal mesh repair [6,12].

The mesh exposure rate in the present study is consistent with that reported for the Elevate system after 2 years of follow-up (2%) [13], and is lower than that in our previous reports with the use of the Perigee/Apogee (12.8% in the hysterectomy group; 3.8% in the uterine preservation group) and Prolift (21.0% in the hysterectomy group; 8% in the uterine preservation group) systems [14,15]. Uterine preservation is another concern during pelvic reconstructive surgery. Several studies have indicated that hysterectomy and uterine preservation have comparable anatomical outcomes and functional Results in pelvic reconstruction with transvaginal mesh [14,15]. Since removing the uterus may not be necessary or beneficial for a prolapse without uterine or cervical disease, uterus-sparing prolapse repair may provide potential advantages including avoiding shortening the vaginal length following hysterectomy, reducing dissection and nerve trauma, and reducing disruption of connective tissues along the vaginal apex [16]. For some women, uterine preservation techniques have potential physical benefits and are also psychologically important. In this study, 81 (73%) of the 111 patients had uterine preservation during transvaginal mesh surgery with the Uphold system.

In this study, it seems like that the incidence of postoperative stress incontinence and overactive bladder was lower than previous studies [6,13]. We had excluded those patients who had occult SUI or preexisting SUI before operation. Thus the patients who had preexisting SUI or urinary dysfunction, even their symptoms got aggravated after POP surgery, were not included in the result analysis. This may be why the incidence of de novo SUI and OAB is relatively low in the present study. As for other postoperative complications, twelve patients (10.8%) had transient urine retention. After surgical dissection of paravesical space, the adjacent tissue could become edematous accompanied with mild hematoma formation. This may lead to bladder dysfunction and poor contraction transiently. Symptoms usually resolved within one month postoperatively in this present study. Besides, 7 patients (6.3%) developed postoperative buttock pain. During our procedure to delivery mesh arms into the sacrospinous ligament, we had to dissect well and confirm the location of ischial spine and sacrospinous ligament. Placing mesh arms too closed to the ischial spine would risk injury to the pudendal nerves and the sciatic nerve. A patient who reports postoperative buttock or gluteal pain may have a pudendal nerve injury. Injury to the branches of the sciatic nerve will result in pain that also radiates down the posterior leg. In these cases, symptoms were all self-limiting under conservative treatments within 6 weeks postoperatively.

Another interesting finding of this study is that the postoperative values of maximum bladder capacity and maximum urethral closure pressure were significantly decreased ($p = 0.002$

and 0.049, respectively). It is possible that prolapse surgery may accentuate or even worsen lower urinary tract symptoms. This could be due to the inevitable partial denervation during paravesical dissection or other unknown factors. Thus although these patients had better voided volume post-operatively, they could not tolerate as much bladder infused capacity as before surgery.

The limitations of the study are the relatively short follow-up of anatomical and functional outcomes, and that it is not a prospective randomized trial.

In conclusion, by using a minimally invasive mesh kit with smaller biomaterial load and feasible uterine preservation, POP reconstruction with the Uphold system yielded an anatomical cure rate of 97.3% after an average of 18.4 months of follow-up (range 12–36 months). More studies are needed to clarify the advantages and disadvantages of vaginal mesh for pelvic reconstruction surgery.

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Conflicts of interest

The authors explicitly state that there is no conflict of interest in connection with this article. None of the authors has received financial support for this study. The Institutional Review Board (IRB: 201700645B0) approved the study.

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