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ORIGINAL ARTICLE

Pelvic organ prolapse repair using the Uphold™ Vaginal Support System: a 1-year multicenter study

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Abstract
Introduction and hypothesis The objective was to assess safety and clinical outcomes in women operated on using the Uphold™ Lite Vaginal Support System.
Methods We carried out a 1-year, multicenter, prospective, single cohort study of 207 women with symptomatic Pelvic Organ Prolapse Quantification (POP-Q) stage ≥2 apical pelvic organ prolapse, with or without concomitant anterior vaginal wall prolapse. Safety data were collected using a standardized questionnaire. Anatomical outcome was assessed by the POP-Q and subjective outcomes by the Pelvic Floor Distress Inventory after 2 months and 1 year using a one-way repeated measures analysis of variance. Pain was evaluated using a visual analog scale.
Results The overall rate of serious complications was 4.3 % (9 out of 207 patients), including 3 patients with bladder perforations, 1 with bleeding >1,000 ml, 2 who had undergone re-operations with complete mesh removal because of pain, and 3 surgical interventions during follow-up because of mesh exposure. POP-Q stage ≤1 after 1 year was 94 % and subjective symptom relief was reported by 91 % of patients ($p < 0.001$). Pain after 2 months and 1 year was 60 % lower compared with the preoperative mean ($p < 0.001$). Minor complications occurred in 20 women (9.7 %) and were dominated by lower urinary tract dysfunction. No predisposing risk factors for complications were found.
Conclusions The Uphold™ Lite procedure in women with apical pelvic organ prolapse provided satisfactory restoration of vaginal topography and symptom relief. However, serious complication rates were largely comparable with those of other transvaginal mesh kits.

Keywords Complications · Mesh · Pelvic organ prolapse

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Introduction

After more than a decade of widespread use, clinical trials have shown that the use of synthetic mesh for pelvic organ prolapse repair generally improves anatomical outcomes and reduces the risk for prolapse recurrence compared with traditional native tissue repair [1, 2]. However, most of these trials also show that the use of mesh, in prefabricated kits or sculptured by the surgeon, significantly increases the risk for both short- and long-term complications compared with traditional surgery [2–4]. Complications may arise as a consequence of the surgical techniques, but also as a result of the mesh itself. Given the serious nature of some complications, the trend toward reducing the biomaterial burden, in addition to finding alternative surgical techniques, has been a priority.

The notion of using large-surface mesh intended to cover pelvic floor defects has undergone some critical revision.

Instead of covering the presumed defects, the importance of apical support in the pathophysiology of pelvic organ prolapse is gaining increased recognition [5]. Rather than being considered an isolated defect, anterior vaginal wall prolapse (cystocele) is often considered a consequence of an undiagnosed apical defect (level I deficiency). Thus, native tissue repair or covering the anterior vaginal tissue defect with mesh without addressing the apical defect may contribute to the unfavorable recurrence rates often described after transvaginal surgery [5]. In line with this reasoning, a biomaterial-augmented surgical intervention to address level I and II deficiencies of the anterior compartment should ideally address both the tissue defect and the lack of support, while at the same time minimizing the intraoperative dissection and postoperative biomaterial load. The device used in the present study, the Uphold™ Lite Vaginal Support System (Boston Scientific), is the second generation of a prefabricated mesh kit that has decreased the biomaterial load to avoid mesh-related complications, but clinical safety data are scarce. The overarching aim of this trial was to provide safety and clinical outcome data in a 1-year follow-up of women with apical pelvic organ prolapse, with or without concomitant anterior vaginal wall prolapse, who underwent application of the Uphold™ Lite system.

Materials and methods

We performed a 1-year, multicenter, prospective, single cohort study from 1 February 2012 through June 2012. The study was performed in 24 centers in Sweden, Finland, Denmark, and Norway, and was approved by the Stockholm Regional Board of Ethics at Karolinska Institutet, Stockholm, Sweden, and by the appropriate ethics committees of all participating clinics. The study was registered at www.clinicaltrials.gov: NCT01823055.

All participating gynecologists were experienced pelvic floor surgeons (at senior consultant level) and had participated in pre-trial hands-on training on the Uphold™ Lite Vaginal Support System. Training included instructor-supervised procedures performed on live patients in operating room sessions. Patients were screened by the operating surgeon for uterine or vaginal vault prolapse (apical prolapse, point C > −1), with or without vaginal anterior wall prolapse ≥ stage 2 (point Ba > −1), according to the Pelvic Organ Prolapse Quantification (POP-Q) system. There were no restrictions with regard to weight, parity, menopausal status, or previous surgery. Exclusion criteria included cervical elongation, previous or current pelvic organ cancer, severe rheumatic disease, insulin-treated diabetes mellitus, connective tissue disorder, and current systemic steroid treatment. No other clinically relevant pelvic disorders for which surgery was indicated, including stress incontinence, cervix elongation, and posterior prolapse were allowed. The surgeon-registered perioperative complications and adverse events during surgery, hospital stay, and follow-up visits in a safety protocol. Internal organ perforation or other injury, bleeding ≥1,000 ml, or adverse events during the follow-up that required re-hospitalization or surgical re-intervention were considered to be major complications. Study forms without any identifying patient data were submitted to the clinical research unit at the Department of Obstetrics and Gynecology, Danderyd Hospital, Stockholm, Sweden, where the data were assembled in a password-protected database. Degree of pelvic organ prolapse was assessed using the POP-Q system at baseline, after 2 months, and after 1 year postoperatively during a gynecological examination in the lithotomy position. Stages 0 and 1 of the apical compartment were considered an optimal anatomical outcome after surgery.

Subjects were followed at 2 months and 1 year after surgery. Most patients were re-examined by the operating surgeon and no blinding was performed. Subjective outcome was assessed after 2 months and 1 year using the Pelvic Floor Distress Inventory 20 (PFDI-20) questionnaire. The PFDI-20 includes 20 questions and three scales (the Urinary Distress Inventory-6 [UDI-6], the Pelvic Organ Prolapse Distress Inventory-6 [PDI-6], and the Colorectal–Anal Distress inventory-8 [CRAD-8]), each of which is scored from 0 to 100, and the overall summary score is gained by adding all the scales together [6].

A total of 207 women underwent a standardized procedure involving the designated mesh kit. The Uphold™ Vaginal Support System utilizes a polyform, lightweight mesh that is made from uncoated monofilament macroporous polypropylene. It is designed to provide level I support at the vaginal apex, while also providing level II support where a concomitant cystocele is likely to occur. The procedural technique was standardized before initiation of the study and was based on a previously described surgical technique [7]. In brief, the Uphold procedure is designed to use a small incision at the vaginal apex, to introduce a Capio® Suture Capturing Device, which helps to connect the mesh to the sacrospinous ligaments and suspend the apex. Preoperatively, the patients received intravenous antibiotic prophylaxis (metronidazole 1 g + cefuroxime 1.5 g). Cystoscopy was performed in 200 out of 207 women (97 %) intraoperatively to rule out bladder injury. Pain was assessed using a visual analog scale (VAS) preoperatively, immediately after the operation, at discharge from the hospital, and at the 2-month and 1-year follow-up visits.

The rate of serious complications was considered to be the primary outcome measure (secondary outcomes included anatomical and subjective outcomes). Based on the results of a previous cohort study by Elmer et al. [6] using Prolift™ we needed to evaluate at least 166 patients to detect a postulated 75 % reduction in the rate of serious complications, with a one-sided type I error of 0.05 and 80 % power (a binary primary outcome), using the less invasive Uphold™ Vaginal Support System. Data on clinical characteristics and

perioperative complications were presented as frequencies (%). The study cohort was divided into subgroups among which complication rates were compared: patients who had Uphold procedures without anterior colporrhaphy; patients who had Uphold and an anterior colporrhaphy; patients without previous surgery for pelvic organ prolapse; and patients who had undergone previous surgery for pelvic organ prolapse. The difference in continuous variables between the groups was assessed using the Mann–Whitney *U* test and in the categorical data using the Chi-squared test. A risk analysis of major and minor complications was performed using a logistic regression model assessing the impact of age, body mass index (BMI), multiparity (≥3 deliveries), concurrent anterior colporrhaphy, previous hysterectomy, and any previous pelvic floor surgery. Results from the risk analysis are presented as odds ratios (ORs) with 95 % confidence intervals (CIs). Comparisons of data among the baseline, 2-month, and 1-year time points were performed using a one-way repeated measures analysis of variance. All analyses were performed using predictive analysis software (PASW) 22.0 (SPSS, Chicago, IL, USA). The study protocol was vetted by the mesh kit manufacturing company before providing an investigator-initiated study grant, but the company had no further influence over the execution of the study, data analyses and interpretation of the data, or in drafting the manuscript. Furthermore, the company provided funding for two investigator meetings held before and after completion of the trial.

Results

Out of 207 women included in the study 137 (66 %) underwent an isolated Uphold procedure, whereas concomitant anterior wall repair by suture technique was performed in 64 women (31 %). The numbers of procedures by individual surgeons ranged between 1 and 14. One patient had a simultaneous perineal reconstruction (in breach of protocol) and in 5 women data on concomitant surgery were missing. Eighty-two women (40 %) had a history of previous anterior colporrhaphy. Clinical baseline characteristics and surgical data are shown in Table 1. General anesthesia was used in 101 women (49 %), spinal anesthesia in 93 women (45 %), epidural anesthesia in 2 women (1 %), and local anesthesia in 7 women (3 %). Operating time was slightly longer in women with concomitant anterior vaginal wall repair (52.4 ± 18.2 min vs 58.8 ± 19.6 min, $p = 0.03$). In a sensitivity analysis we compared patients who participated in follow-up at 1 year with those who did not and found no significant differences with regard to patient characteristics or POP-Q staging at baseline or at the 2month follow-up (data not shown).

Detailed complication rates are shown in Table 2. The overall rate of serious complications was 4.3 % (9 out of 207 women). Although our results corresponded to a 33.8 % reduction in serious complications compared with the study by Elmer et al. [6] (6.5 %; 17 out of 261 patients), the reduction was not statistically significant ($p = 0.42$). Three bladder perforations were discovered at cystoscopy, 2 of which occurred during dissection and 1 by the Capio® instrument when connecting the mesh to the sacrospinous ligament. In 7 women bleeding exceeded 500 ml, but in 1 patient there was a bleeding in excess of 1, 000 ml, requiring inferior pudendal artery embolization. Two women needed re-operation during the initial hospital stay, in both cases because of severe pain and both patients required complete mesh removal. Minor complications occurred in 20 women (9.7 %), and 6 women (2.9 %) had more than one minor complication. The most common minor complication was bladder-emptying difficulties (12 women, 5.7 %) followed by hematomas in 4 women (2 %; see Table 6). The complication rates did not differ in women with isolated mesh surgery compared with those with concomitant anterior suture repair, or in

Table 1 Cohort characteristics ($N = 207$)

	All	Uphold™	Uphold™ and anterior colporrhaphy
n	207	137	64
Age (years)	66.3 ± 9.2	66.1 ± 9.1	67.2 ± 8.0
Weight (kg)	70.1 ± 9.4	69.8 ± 9.5	70.2 ± 9.5
BMI	25.3 ± 4.6	25.3 ± 4.4	25.6 ± 4.6
Parity median	2 (0–5)	2 (0–5)	2 (0–5)
Multiparous (≥3 deliveries)	79 (38)	57 (42)	21 (33)
Menopause	188 (91)	123 (90)	61 (95)
Smokers	12 (6)	9 (7)	3 (5)
Somatic diseases			
No diseases	68 (33)	50 (36)	18 (28)
Cardiovascular diseases	81 (39)	53 (39)	28 (44)
Thyroid dysfunction	21 (10)	13 (9)	7 (11)
Asthma	12 (6)	8 (6)	3 (5)
Diabetes	4 (2)	4 (3)	0 (0)
Fibromyalgia and rheumatism	6 (3)	3 (2)	2 (3)
Other	4 (2)	3 (2)	1 (1)
Previous surgeries			
Hysterectomy	79 (38)	53 (39)	22 (34)
Any previous pelvic floor surgery	88 (43)	53 (39)	32 (50)
Hysterectomy and incontinence surgery or anterior colporrhaphy	39 (19)	23 (17)	15 (23)
Operating time (min)	54.6 ± 18.8	52.4 ± 18.2*	58.8 ± 19.6*
Bleeding (ml)	78 ± 122	82.1 ± 138.6	69.0 ± 83.0
Hospital stay (days)	2 (1–7)	2 (1–7)	2 (1–5)

In 6 women information on concomitant operations was missing

Data shown as *n* (%), means ± SD, or median (range)

*$p = 0.03$

Table 2 Complications after Uphold™ Lite mesh kit surgery

	All	Uphold™	Uphold™ and colporrhaphy anterior	First operation	Recurrence
N (%)	207	137	64	125	82
Intraoperative complications					
Bladder perforation	3 (1.5)	2	1	2	1
Urethra or rectum perforation	0	0	0	0	0
Bleeding ≥500 ml	7 (3.3)	5	2	5	2
Bleeding ≥1,000 ml	1 (0.5)	1	0	1	0
Postoperative complications					
Urinary tract infection	1 (0.5)	0	1	1	0
Bladder-emptying difficulties	12 (5.7)	12	0	9	3
Catheter after hospital stay	5 (2.4)	3	2	2	3
Anemia (hemoglobin less than 100 g/L)	0	0	0	0	0
Fever (≥3 days)	1 (0.5)	1	0	1	0
Wound infection	0	0	0	0	0
Groin pain	2 (1)	1	1	1	1
Vaginal hematoma	3 (1.4)	2	1	1	2
Deep venous thrombosis	0	0	0	0	0
Cardiovascular problems	1 (0.5)	1	0	0	1
Pelvic hematoma	2 (1)	1	1	1	1
Re-operation[a]	2 (1)	2	0	2	0
Others[b]	3 (1.5)	2	1	3	0

[a] Re-operations: both patients underwent mesh removal owing to severe postoperative pain

[b] Pain in the coccygeal vertebra, $n=1$; constipation, $n=1$; stress incontinence, $n=1$

women undergoing primary pelvic organ prolapse surgery compared with those operated on because of recurrence. We could not find any predisposing risk factor for either major or minor complications when evaluating age, multiparity, BMI, concomitant anterior colporrhaphy, previous hysterectomy, and previous pelvic floor surgery (data not shown).

Thirty-five (17 %) women had unscheduled visits to the hospital during the 2 initial postoperative months. The most common reason was lower urinary tract dysfunction (urinary tract infection, $n=8$; voiding dysfunction, $n=5$; incontinence, $n=4$). Other reasons included pain ($n=4$), mesh exposure ($n=3$), vaginal bleeding ($n=2$), and constipation ($n=1$). Between the 2-month and 1-year follow-up, 28 women (13 %) visited the hospital. Lower urinary tract dysfunction was still the most common complication (midurethral sling procedures, $n=5$; other incontinence-related visits, $n=5$; and recurrent urinary tract infections, $n=2$) followed by pain problems (pelvic pain, $n=2$; vulva pain, $n=1$; groin pain, $n=1$;

Table 3 Pelvic Organ Prolapse Quantification (POP-Q) staging pre- and postoperatively in all women and according to the operation model

	Preoperatively ($N=207$)			2 months ($N=172$)			1 year ($N=164$)		
	All	U	U+C	All	U	U+C	All	U	U+C
Stage 0	–	–	–	80 (46)	54 (47)	25 (45)	62 (38)	41 (37)	21 (42)
Stage 1	–	–	–	77 (45)	51 (45)	26 (47)	92 (56)	64 (58)	25 (50)
Stage 2	71 (34)	43z (32)	25 (39)	10 (6)	6 (5)	3 (6)	3 (2)	0 (0)	2 (4)
Stage 3	115 (56)	84 (61)	29 (45)	5 (3)	3 (3)	1 (2)	5 (3)	4 (4)	1 (2)
Stage 4	21 (10)	10 (7)	10 (16)	–	–	–	2 (1)	1 (1)	1 (2)

In 6 women information on concomitant operation was lacking

Data shown as *n* (%)

U patients having the Uphold™ procedure only, *U+C* patients having the Uphold™ procedure with a concomitant anterior colporrhaphy

Table 4 POP-Q outcomes according to whether or not the patient underwent the procedure for recurrent prolapse

	Preoperatively ($N=207$)		2 months ($N=172$)		1 year ($N=164$)	
	F	R	F	R	F	R
Stage 0	–	–	44 (40)	36 (57)	34 (34)	28 (43)
Stage 1	–	–	53 (49)	24 (38)	59 (59)	33 (51)
Stage 2	37 (30)	34 (41)	7 (6)	3 (5)	2 (3)	1 (2)
Stage 3	77 (61)	38 (47)	5 (5)	0 (0)	3 (3)	2 (3)
Stage 4	11 (9)	10 (12)	–	–	1 (1)	1 (1)

Data shown as *n* (%)

F patients with a first operation, *R* previous anterior wall repair

dyspareunia, $n=1$). Reoperation for prolapse recurrence between the 2-month and 1-year follow-up occurred in a total of 7 patients, 2 patients for recurrent apical prolapse, 4 had posterior vaginal wall repair, and 1 patient anterior vaginal wall repair. After the 2-month follow-up visit 3 patients underwent surgical revision of the mesh because of exposure, during which the exposed mesh was excised and the mucosa readapted.

Pain assessed by the VAS was lower preoperatively (1.0 ± 1.7) as compared with immediately after the operation 2.6 ± 2.8 ($p<0.001$) and at the time of hospital discharge 1.6 ± 1.9 ($p=0.004$). At 2 months and 1-year follow-up the VAS was reduced compared with the baseline (0.4 ± 1.0, $p<0.001$, and 0.4 ± 0.9, $p<0.001$ respectively).

Anatomical outcomes are presented in Tables 3–5. At the 2-month follow-up a comprehensive complete POP-Q evaluation was available in 172 women (83 %) and at 1-year follow-up in 164 women (79 %). After 2 months 157 out of 172 women (91 %) and after 1 year 154 out of 164 women (94 %) had an optimal anatomical outcome at the vaginal apex (Table 3). When we considered all missing patients as failures, a successful outcome was achieved in 75 and 74 % at 2 months and 1 year respectively. When viewed separately, both the anterior and middle vaginal compartments showed significant improvements ($p<0.001$), whereas the position of the posterior vaginal compartment did not differ statistically from baseline (Table 4). There was no significant difference in anatomical outcomes when comparing women who had undergone an isolated Uphold procedure versus those with a concomitant anterior wall repair, or women undergoing a primary pelvic prolapse operation versus those having an operation to treat a recurrence (Tables 4, 5). After 1 year there were 37 cases of de novo prolapse, 32 of which occurred in the posterior compartment and the majority ($n=26$) consisted of a stage 2 prolapse. De novo prolapse occurred independently of the operation mode or a history of previous anterior wall suture repair.

Subjective outcomes are presented in Table 6. Preoperatively, pelvic organ prolapse and urinary symptoms caused most distress. At the 2-month follow-up these symptoms were significantly relieved, whereas colorectal–anal distress did not show an improvement at this point. At the 1-year follow-up all subscales were improved and 165 out of 181 women (91 %) showed a higher total score (i.e. improved overall) compared with baseline.

Discussion

In this prospective multicenter cohort study we found that the Uphold™ Lite Vaginal Support System significantly improved anatomical outcomes in patients with an apical defect, with or without anterior vaginal wall prolapse, 1 year after surgery. However, serious complication rates with the Uphold™ Lite system were largely comparable with those previously reported for other transvaginal mesh kits.

With an overall serious complication rate of 4.3 %, we failed to reach the postulated reduction in serious complications using the Uphold™ Lite Vaginal Support System in comparison with a prospective cohort study on Prolift® [6]. Although we achieved a decrease in serious complications by one third compared with the Prolift®, this did not reach statistical significance. The decrease mostly derived from fewer intraoperative bladder perforations and fewer surgical interventions to treat mesh complications during follow-up. For transvaginal Prolift® mesh, bladder perforation rates range between 0 and 2 % [8–10] and for ten different pooled kits this rate was reported to be 0.8 % [11]. A strength of our study was that bladder injury was confirmed or refuted by cystoscopy in nearly all patients and it may be assumed that the occurrence of 1.5 % bladder perforations is accurate. Similarly, the rate of bleeding complications was in line with previous reports on other transvaginal mesh kits and did not cause any long-term sequelae [8, 9, 11]. However, given that one patient required emergency embolization of a uterine arterial branch because of profuse hemorrhage during surgery, the question of which interventional resources should be available when performing trocar-guided mesh kit procedures is raised again.

Table 5 Distribution of POP-Q scores pre- and postoperatively

	Preoperatively	2 months	1 year	*p* (preoperatively to 2 months)	*p* (preoperatively to 1 year)
Aa					
All	1 (−3 to +3)	−2 (−3 to +2)	−2 (−2 to +3)	<0.001	<0.001
Uphold	1 (−3 to +3)	−2 (−3 to +2)	−2 (−3 to +3)	<0.001	<0.001
Uphold + colporrhaphy	1 (−3 to +3)	−2 (−3 to +2)	−2 (−3 to +2)	<0.001	<0.001
Ba					
All	1 (−3 to +4)	−2 (−3 to +6)	−2 (−3 to +8)	<0.001	<0.001
Uphold	1 (−2 to +4)	−2 (−3 to +6)	−2 (−3 to +8)	<0.001	
Uphold + colporrhaphy	1 (−3 to +4)	−2 (−3 to +2)	−2 (−3 to +2)	<0.001	<0.001
C					
All	0 (−8 to +7)	−5 (−9 to +9)	−5 (−9 to +8)	<0.001	<0.001
Uphold	0 (−8 to +7)	−5 (−9 to +9)	−5 (−9 to +8)	<0.001	<0.001
Uphold + colporrhaphy	0 (−6 to +7)	−5 (−9 to +8)	−5 (−8 to +8)	<0.001	<0.001
D					
All	−2 (−11 to +10)	−4 (−10 to +10)	−6 (−11 to +10)	<0.001	0.01
Uphold	−2 (−11 to +10)	−6 (−10 to +10)	−7 (−11 to +10)	<0.001	0.02
Uphold + colporrhaphy	−2.5 (−9 to +9)	−6 (−9 to +9)	−6 (−10 to +9)	0.009	0.4
Ap					
All	−2 (−3 to +3)	−2 (−3 to +3)	−2 (−3 to +3)	1.0	0.07
Uphold	−2 (−3 to +3)	−2 (−3 to +3)	−2 (−3 to +3)	1.0	0.4
Uphold + colporrhaphy	−2 (−3 to +3)	−2 (−3 to +2)	−2 (−3 to +1)	1.0	0.1
Bp					
All	−2 (−3 to +5)	−2 (−4 to +3)	−2 (−3 to +3)	1.0	1.0
Uphold	−2 (−3 to +5)	−2 (−3 to +3)	−2 (−4 to +3)	1.0	1.0
Uphold + colporrhaphy	−2 (−3 to +4)	−2 (−4 to +3)	−2 (−3 to +2)	1.0	1.0
Gh					
All	4 (2 to 10)	4 (2 to 8)	4 (2 to 7)	0.01	<0.001
Uphold	5 (2 to 7)	4 (2 to 7)	4 (2 to 7)	0.2	0.03
Uphold + colporrhaphy	4 (3 to 10)	4 (2 to 6)	4 (2 to 7)	0.005	<0.001
Pb					
All	3 (1 to 6)	3 (2 to 6)	3.5 (2 to 6)	0.09	0.03
Uphold	3 (2 to 6)	3 (2 to 6)	3 (2 to 5)	0.2	0.3
Uphold + colporrhaphy	4 (1 to 6)	3 (2 to 6)	4 (2 to 6)	0.8	0.1
Tvl					
All	8 (5 to 11)	8 (5 to 11)	8 (5 to 11)	0.3	0.7
Uphold	8 (5 to 11)	8 (5 to 11)	8 (5 to 11)	0.5	1.0
Uphold + colporrhaphy	8 (5 to 10)	8 (5 to 10)	8 (6 to 11)	1.0	1.0

Data shown as median (range)

Minor complications occurred in almost 10 % of patients and were dominated by voiding difficulty, which is the most common postoperative complication also seen with the use of other mesh kits [9, 12]. The operation inherently alters the position of the urethra and bladder, which in turn may lead to functional changes and bladder-emptying difficulties. On the other hand, pelvic organ prolapse surgery, especially using transvaginal mesh [13], is associated with a risk for de novo urinary incontinence, which has been estimated to occur in 22 to 41 % of patients [14, 15]. In the present study, the total number of de novo incontinence (6 %) was quite low and it seems that the negative effects on the urethral closing mechanism of the procedure is less pronounced compared with large-scale mesh techniques, which require a larger dissection area. Using the PFID-20, we actually observed an overall improvement in stress urinary incontinence postoperatively. This is presumably related to the smaller dissection area and limited tissue separation needed to place the suspending mesh [14].

Table 6 Pelvic floor distress inventory questionnaire results

	Preoperatively	2 months	*p**	1 year	*p**	*p***
Pelvic Organ Prolapse Distress Inventory	44.4 ± 20.3	15.7 ± 17.4	<0.001	10.9 ± 13.2	<0.001	<0.001
Colorectal–anal Distress Inventory	22.2 ± 18.1	21.6 ± 16.7	1.0	14.1 ± 35.5	<0.001	<0.001
Urinary Distress Inventory	36.4 ± 21.4	21.0 ± 18.1	<0.001	16.9 ± 17.0	<0.001	0.006
Total	103.1 ± 49.4	51.1 ± 39.5	<0.001	42.8 ± 37.1	<0.001	0.008

Data shown are mean ± SD

**p* value versus baseline

***p* value versus 2 months

We could not find any significant risk factors for either major or minor complications. In a previous transvaginal mesh study, concomitant pelvic floor surgery increased the risk for minor complications, such as urinary tract infection, urine retention, fever, groin pain, and vaginal hematoma [9]. In that study, concomitant surgery was performed in 24 % of the women, of which hysterectomy was most common. It is possible that the longer operation time and larger dissection area might explain the increased minor complication risk in women with concomitant procedures [9]. In the present study, only additional cystocele repair was permitted, but the complication rates in women who had undergone mesh kit surgery alone and those who had concomitant cystocele repair did not differ significantly.

Decreasing the mesh biomaterial load in prefabricated kits, such as the product used in the current study, may avert some of the complications associated with transvaginal mesh repair [3]. In the long term, pelvic pain subsequent to mesh surgery may be very difficult to treat successfully, and is one area where a decrease in biomaterial load may lower the risk. In our study, we experienced 2 cases of severe pelvic pain immediately after surgery requiring re-intervention and complete removal of the mesh. However, only 1 patient recovered subsequent to mesh removal, whereas the other experienced severe pain for the duration of the follow-up, presumably because of pelvic nerve injury. Although still anecdotal, there may be an association between pain complications and other somatic pain manifestations before surgery, but most pain complications are probably a result of the procedure itself. In the present study, we only had 3 cases (1.4 %) of mesh erosions/exposures requiring surgical intervention during follow-up, suggesting a benefit of the Uphold™ system compared with large surface-covering mesh kits. Continued biomaterial development toward lightweight, partially absorbable meshes, proper training on the product in use, and sufficient surgical volumes may further decrease the risk for mesh complications [4]. However, in contrast to postoperative pelvic pain, exposure itself is often relatively simple to handle and rarely a cause of debilitating symptoms [16].

Surgeon experience has been suggested to be an important factor in the occurrence of mesh complications [17] and to some extent this may have influenced our results. It has been shown that there is a negative linear association between the number of mesh operations performed and complications [17], and guidelines suggest that only trained surgeons should perform prolapse mesh surgery [18]. All investigators in the present study were experienced pelvic surgeons and had undergone hands-on training before the study. Nonetheless, the level of expertise with the actual product in use and the number of patients included per surgeon varied widely. It is plausible that a trial with a similar design, but restricted to centers with large numbers of mesh procedures, would yield lower complication rates. Such a design, however, would not reflect the clinical reality in many countries where mesh surgery is widespread and would not yield outcomes that mirror current practice upon which patient preoperative counseling should be based. We studied a relatively large number of women in a multicenter setting, which is a strength of our study, but we nonetheless recognize that we studied a selected group of patients and findings may not be generalizable to the general population. Additional limitations of our study include the lack of outcome assessor blinding, which may have introduced a certain degree of bias, the exclusion criteria that limit the generalizability of our findings, and that outcome assessors in some cases had conflicts of interests. Loss to follow-up at 1 year was around 20 %, which prompted a sensitivity analysis in which we found no differences in patient characteristics or clinical findings at baseline or at the 2-month follow-up between patients who participated in follow-up and those who did not.

The topography of both the anterior and middle vaginal compartments improved significantly following the Uphold™ Lite operation. In over 90 % of women postoperative POP-Q stage 0 or 1 of the vaginal apex was achieved by 1 year after surgery, which is largely comparable with previous studies using other synthetic mesh kits, in which the overall rates of POP-Q stage 0–1 range between 79 and 94 % with Prolift® [8, 19], and 92–99 % for Anterior Elevate® [20, 21]. These results, however, are not directly comparable with the women in our study, because in the previous studies, all vaginal compartment repairs (anterior, posterior, and combined)

were allowed. When considering all patients lost to follow-up as failures in our analysis the anatomical success rate was 74 % at 1 year, and if considering stage 2 in any vaginal compartment as a failure the anatomical success rate was 71 % at 1 year.

Abdominal sacrocolpopexy has widely been considered the gold standard for the treatment of apical prolapse. Short- to mid-term (6 months to 3 years) anatomical success rates have been reported to range between 78 and 100 % [22], with gradually increasing failure rates as the duration of follow-up increases [23]. Because of the relatively high morbidity and long recovery associated with laparotomy [24], laparoscopic and robot-assisted operative techniques have increased in recent years. The mean short- to mid-term success rates with both laparoscopic and robot-assisted sacrocolpopexy have been over 90 %, ranging from 60 to 100 % [25]. With regard to anatomical outcomes we found that the Uphold™ Lite operation technique had comparable outcomes to those reported after laparoscopic or robot-assisted sacrocolpopexy after 1 year. At present, there are no randomized studies comparing these approaches, and because of the high efficiency of these procedures, any head-to-head comparison would require a very large number of patients to show statistically and clinically meaningful differences between the procedures.

Although the rate of de novo prolapse after 1 year was 24 %, most de novo cases were stage 2, i.e., included cases with the vaginal wall inside the hymen, and presumably did not cause severe distress. This was reflected by the few patients undergoing secondary surgery during the follow-up period. The postoperative phenomenon of de novo prolapse in untreated compartments is well known; yet, our numbers were lower than those reported for anterior Prolift® (54 %) [26]. Apical support may be particularly important for the anterior vaginal wall and efficient apical correction reduces the risk for prolapse in the anterior compartment, as seen in an anatomical model [27].

After 1 year, subjective symptom improvement was achieved in 91 % of our patients. To the best of our knowledge, no previous studies on the mesh kit used in the present study have assessed quality of life aspects; yet again, other vaginal mesh operations have resulted in improvements in quality of life comparable with those in our study [7, 28]. Preoperatively, the most distressing symptoms were related to lower urinary tract dysfunction and pelvic organ prolapse, which both to a large extent were relieved after surgery.

In conclusion, at 1 year, the serious complication rate using the Uphold™ Lite Vaginal Support System was 4.3 %, which is largely comparable with those reported for other transvaginal mesh kits. The objective success rate was 94 % at the apex and 71 % when any de novo prolapse, regardless of compartment, was included. Further studies are now needed to assess long-term safety and efficacy outcomes, in addition to direct comparisons with laparoscopic/robotic suspension procedures in the treatment of apical defects.

Compliance with ethical standards

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