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INTRA- AND PERIOPERATIVE MORBIDITY FOLLOWING PELVIC ORGAN PROLAPSE REPAIR USING A TRANSVAGINAL SUTURE CAPTURING MESH DEVICE COMPARED TO TROCAR GUIDED TRANSVAGINAL MESH AND TRADITIONAL COLPORRAPHY

Hypothesis / aims of study
Current trends in mesh augmented pelvic reconstructive surgery has two main focuses: first, to reduce the implant biomaterial load in order to decrease mesh related complications, and second, to develop less invasive surgical techniques to place the mesh in position in order to decrease the rate of complications during surgery. In theory, the transvaginal suture capturing mesh device (Uphold™ LITE) for repair of level I-II apical/anterior vaginal wall prolapse, satisfy both of these demand s but fundamental documentation on clinical efficacy and safety of the product is lacking. The aim of this analysis was to describe intra- and perioperative safety and morbidity associated with the Uphold™ LITE system as compared to traditional suture repair and trocar guided transvaginal mesh (Prolift™ Anterior).

Study design, materials and methods
Data for the present analysis was derived from two different trials: a randomised controlled trial (RCT) and a prospective cohort study. The RCT was a multicentre (53 clinics), parallel-group, single blinded, controlled trial where use of a trocar-guided, transvaginal polypropylene-mesh repair kit (Prolift™ Anterior) was compared to traditional colporraphy in women with prolapse of the anterior vaginal wall (cystocele).(1) The second study was designed as a prospective multicentre (24 clinics), open-label, single cohort assessment of a transvaginal mesh and suture capturing device system (Uphold™ LITE) repair of middle compartment prolapse (vaginal vault or uterine prolapse) with or without cystocele.
In both trials, patients were screened by participating surgeons for prolapse of the anterior vaginal wall/ upper vaginal compartment (vaginal apex or uterine descent) in the outpatient clinic. In the RCT, patients were invited to participate if they presented primary or recurrent prolapse of the anterior compartment ≥ stage 2 according to the Pelvic Organ Prolapse Quantification (POP-Q) system and experienced symptoms of vaginal bulging. In the cohort study the corresponding inclusion criteria was primary or recurrent ≥ stage 2 prolapse of the middle compartment (vaginal vault or uterine prolapse), with or without a cystocele. Oral and written informed consent was obtained from all participants before entering the study. Exclusion criteria for both trials included previous cancer of any pelvic organ, systemic glucocorticoid treatment, insulin treated diabetes, an inability to participate in study follow-up or to provide informed consent.
Before study start, pelvic surgeons underwent supervised hands-on training in live operating room sessions and all operating surgeons were at senior consultant level. All three surgical procedures (colporraphy, Uphold™ LITE and Prolift™ Anterior) were standardised prior to initiation of the studies. No training sessions were permitted on patients participating in the trial. Baseline patient characteristics, demographic data, and medical history were collected using a questionnaire. A standardized protocol was used to describe complications during the surgical procedures and adverse events during the associated hospital stay (completed by the surgeon). In the prospective suture capturing mesh device study, cystoscopy and rectal palpation was routinely performed intra-operatively.
The Uphold™ LITE vaginal support system is an intra-vaginal approach to apical and anterior vaginal wall prolapse repair that utilizes a suture capturing device to place the mesh.(2) After primary dissection the suturing device is used to pull the mesh through the sacrospinous ligament, medial to the ischial spine. An anterior colporraphy was allowed following the Uphold™ LITE procedure at the discretion of the surgeon if deemed necessary. The Prolift™ Anterior system is a trocar-guided approach to pass mesh fixation arms through the arcus tendineus fascia pelvis by the obturator apertures.(3)

Results
In the RCT 200 patients underwent prolapse repair with the transvaginal mesh kit (mean age 64.3 years, SD 9.8) and 189 patients underwent traditional colporraphy (mean age 65.1 years, SD 9.8). In the suture capturing mesh device trial a total of 202 patients were included (mean age 66.3 years, SD 9.3). Demographic characteristics were similar in the three treatment groups.
In the Uphold™ LITE trial, 193 patients (96%) underwent cystoscopy and 191 (95%) rectal palpation intra-operatively. There were 3 cases (1.5%) of bladder injury and no cases of bowel injury. One patient had a cardiovascular event (atrial fibrillation) early during surgery (non-procedural related) and the operation was postponed. There was one case of device malfunction leading to substitution of the suture capturing device. Postoperatively, there were two cases (1%) of re-operation because of pelvic pain and in one case the mesh was removed on day 4 after surgery. One patient had a cardiovascular event during the hospital stay (myocardial infarction).

Table 1. Intra- and perioperative complications of mesh devices in comparison to colporraphy.

	Colporraphy n= 189	**Prolift n= 200**	**P-value***	**Uphold n= 202**	**P-value***
Bladder injury	1 (0.5)	7 (3.5)	0.07	3 (1.5)	0.62
Bleeding >1000 mL	0	1 (0.5)	1.00	1 (0.5)	1.00
Pelvic pain	0	5 (2.5)	0.06	1 (0.5)	1.00
UTI	4 (2.1)	4 (2.0)	1.00	2 (1.0)	0.44
Bladder emptying difficulties	6 (3.2)	16 (8.0)	0.05	11 (5.4)	0.33

Infection of unclear origin	0	1 (0.5)	1.00	1 (0.5)	1.00
Pelvic hematoma	0	1 (0.5)	1.00	1 (0.5)	1.00
Catheter after hospital stay	0	2 (1.0)	0.50	3 (1.5)	0.25
Vaginal reoperation	0	2 (1.0)	0.50	2 (1.0)	0.50

Figures are number of patients (%). *Comparison with colporraphy.

Although associated with an overall lower complication rate, there were no statistically significant differences between Uphold™ LITE and Prolift™ Anterior with regard to perioperative adverse events (P-values not shown).

Interpretation of results

There were no significant differences between the Uphold™ LITE system repair of anterior/middle compartment prolapse and traditional colporraphy with regard to intra- and perioperative morbidity. The procedure decreased the complication rates compared to anterior trocar-guided transvaginal mesh but the differences were not statistically significant. The most frequent postoperative adverse event was bladder emptying difficulties.

Concluding message

Our analysis suggest that a suture capturing mesh device for repair of middle compartment prolapse, with or without cystocele, can be used in a multicenter setting with a relatively low rate of serious perioperative complications after instructor- supervised hands-on training sessions.

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Disclosures

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