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The Manchester procedure: anatomical, subjective and sexual outcomes

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Abstract

Introduction and hypothesis Classical native-tissue techniques for pelvic organ prolapse (POP) repairs, such as the Manchester procedure (MP), have been revitalized because of vaginal mesh complications. However, there are conflicting opinions regarding sufficient apical (mid-compartment) support by the MP and concerns about the risk of dyspareunia. The aims of this study were therefore to investigate anatomical and patient-reported outcomes 1 year after MP.

Methods Prospective cohort study of 153 females undergoing an MP for anterior compartment POP between October 2014 and June 2016. Pre- and 1-year postoperative evaluations included POP-Q measurements and the questionnaires Pelvic Floor Distress Inventory Short Form 20 (PFDI-20) and POP/Urinary Incontinence Sexual Questionnaire (PISQ-12).

Results At 1 year, 97% (148/153) attended the follow-up. Significant anatomical improvements (p < 0.01) were obtained in all compartments. Mean Ba was $-1.1 (\pm 1.4)$, mean C $-5.9 (\pm 1.7)$ and mean D $-7.0 (\pm 1.2)$ at follow-up. Point C ≤ -5 was present in 81.1%. POP-Q stage 0–1 was obtained in 99.3% in the mid-compartment (C < -1), but only in 48.6% in the anterior compartment (Ba < -1). A significant reduction in symptom scores was obtained for PFDI-20 (p < 0.01) and PISQ-12 (p = 0.01). No significant changes were seen in dyspareunia rates (q.5, PISQ-12), but 5.6% reported de novo dyspareunia. Concerning POP symptoms, 96.0% reported being cured or significantly improved.

Conclusions The Manchester procedure provides adequate apical support, albeit inferior anatomical anterior compartment results, and 96.0% reported being subjectively cured or substantially better at 1-year follow-up, with no significant change in dyspareunia.

Keywords Dyspareunia · Gynecologic surgical procedures · Pelvic organ prolapse · Recurrence

Introduction

Symptomatic pelvic organ prolapse (POP) affects a large proportion of the female population, with anterior compartment prolapse representing the most common form [1]. The incidence of POP surgery ranges from 1.5 to 1.8 per 1000 women years, peaking at the age of 60–69 [2]. High recurrence rates,

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particularly in the anterior compartment, have been a major dilemma in POP surgery for over a century [3]. There is to date no consensus on which surgical techniques to use for which indications [4]. Concomitant apical repair has been shown to improve outcomes after anterior repairs [5], but there are widely differing views among vaginal surgeons on how to successfully elevate and secure the vaginal apex and whether or not a hysterectomy should be performed [4].

In recent years, several authors have refuted the previously alleged poor outcomes after uterus-sparing native tissue POP repairs [6], and native-tissue procedures such as the Manchester procedure (MP) are again gaining popularity particularly becuase of the steady increase in reported complications after vaginal mesh surgeries [7]. There are, however, concerns that an MP might not give adequate elevation of the mid-compartment [8], and some claim it is primarily useful for correcting cervical elongation [9]. Since the procedure was modified shortly after its inception to incorporate a restoration of the perineal body (to act as support for the anterior

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repair), it has been associated with a risk of dyspareunia, especially when levator ani muscle plication is used [10].

In our department, the MP has been the surgical technique of choice for anterior compartment POP for decades. Our tertiary center performs about 150 Manchester procedures yearly. In sexually active women, our department recommends reconstruction of the perineal body without involving the levator ani muscles [11] to reduce the dyspareunia risk. The department has run an internal quality registry for POP surgery since 2002, and we have previously reported our results from this registry on women who had undergone native tissue repairs [11]. Our published registry data revealed significantly better outcomes in women with POP operated on with the MP compared with isolated repairs in the anterior compartment, especially in terms of a low rate of symptomatic recurrences in need of re-operation [11]. However, like other recent publications reporting favorable outcomes after the MP, the study was mainly retrospective in design [11, 12].

Our aim was therefore to evaluate anatomical and subjective POP-related and sexual outcomes 1 year after the Manchester procedure in a prospective observational study, with adequate sample size. We also aimed to assess whether postoperative anatomical success was correlated with subjective outcomes.

Materials and methods

The present study was a prospective cohort study of women operated on with the Manchester procedure (MP) at the Department of Gynecology at Oslo University Hospital (OUS). Inclusion was carried out between October 2014 and January 2016, and surgeries were performed between October 2014 and June 2016. Patients referred for a preoperative evaluation of POP received postal study information prior to their appointment at the outpatient clinic. Women with symptomatic prolapses that included the anterior compartment and with no previous prolapse surgery were considered eligible for the study. Patients were excluded if they had previously undergone a hysterectomy (total or subtotal) or if the preoperative evaluation (including transvaginal ultrasound and, on indication, endometrial biopsy) revealed coexisting indications for hysterectomy, such as endometrial pathology. In case of adnexal pathology, evaluation and treatment for this condition had to be concluded before POP surgery.

As the standard treatment for anterior compartment prolapse with a concomitant mid-compartment prolapse up to stage 3 due to cervical elongation at our department is the MP, study participation had no impact on the choice of surgical method for these patients. Although MP can be performed in larger uterine prolapses, the routine procedure at the department for the few POP patients evaluated for surgery (< 10% [11]) with a true uterine prolapse (\geq stage 2) and not only cervical elongation is a hysterectomy in combination with either sacrospinous fixation or sacrocolpopexy. These women were excluded from study participation. The position of the uterine corpus was evaluated on palpation (during patient Valsalva maneuver or by cervical traction) by identifying the cervico-uterine junction as well as the position of the posterior fornix. The study participants had to be fluent in one of the Scandinavian languages or English to be included. The present study was approved by the Norwegian Regional Ethics Committee (2013/2093) and Oslo University Hospital (OUS) personal data officer. It was registered at ClinicalTrials.gov with registry no. NCT02246387. Informed written consent was obtained from all participants.

The Manchester procedure was developed in the late nineteenth century as a uterus-sparing surgical option for POP. It includes an anterior colporrhaphy followed by a uterosacral/ cardinal ligament plication in which the ligaments are shortened and repositioned on the proximal anterior aspect of the cervix allowing it to be drawn upwards, inwards and backwards in the female pelvis; see Fig. 1. This shortening and repositioning of ligaments provide the elevation of the mid-compartment. The extent of cervical amputation depends on the degree of cervical hypertrophy and is not essential for surgical success when the cervix is of normal length. Following cervical amputation, a Hegar dilatator in the cervical canal prevents accidental closure while reconstructing the portio with modified Sturmdorf sutures. In recent publications, the term Manchester procedure is often used without including a reconstruction of the perineal body [12], possibly omitted to avoid dyspareunia. In our department (and in this study), we reconstruct the perineal body if it is reduced in height and thickness, even in the absence of a posterior wall prolapse, as described in the original papers on the procedure [13]. The rationale for this is that such anatomical changes will result in a change of the vaginal axis and a subsequent loss of support for the anterior compartment [14]. The few patients with anterior or mid- compartment POP and a completely intact perineal body were not included in this study.

Before surgery, and at the 1-year follow-up, a standardized interview and a clinical examination that included POP-Q measurements [15] were performed. In addition, all patients filled out the study questionnaire on POP-related symptoms (PFDI-20) [16], and those who were sexually active in terms of vaginal intercourse also filled out a questionnaire on sexual dysfunction (PISQ-12) [17]. The Norwegian validated version of PFDI-20 [18] had not been published at the initiation of this study, and PISQ-12 is still not validated to Norwegian. Therefore, translations of the validated Swedish (closely related to Norwegian linguistically and culturally) versions were used [19]. The original English versions were offered to patients not fluent in one of the Scandinavian languages, but who were eloquent in English. Pre- and postoperative complications were registered at the 1-year follow-up. To reduce the risk of bias, the 1-year postoperative assessments were not performed by the surgeon, but by another clinician at the department.

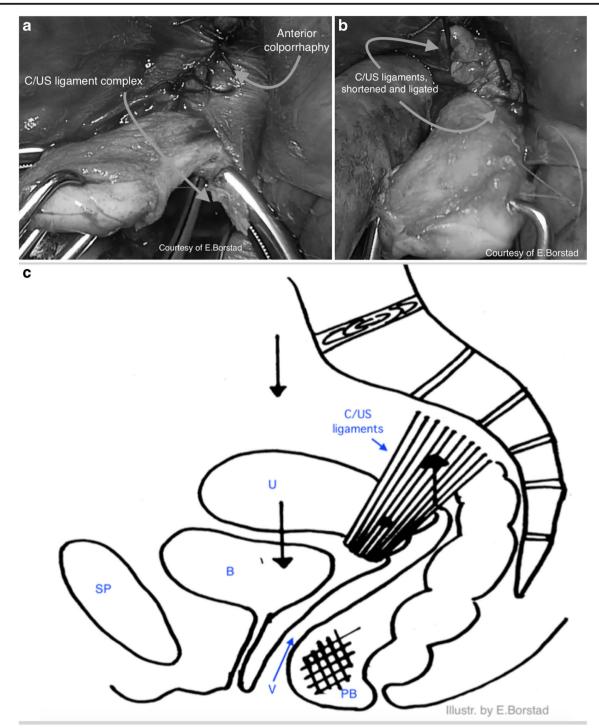


Fig. 1 Manchester procedure. a Clamping and dissection of the cardinal and uterosacral (C/US) ligament complex. b C/US ligaments shortened and attached at anterior aspect of the isthmic part of the uterus. c

Supportive effect of uterus-sparing surgery and reconstruction of the perineal body. SP = symphysis pubis; B = bladder; U = uterus; V = vagina; C/US ligaments = cardinal/uterosacral ligaments

Our primary outcomes at the 1-year follow-up were the percentage of patients with POP-Q stage 0–1 in the mid- and anterior compartment as well as the percentage of women with point $C \leq -5$ (eqivalent to stage 0). Secondary outcomes were mean changes in POP-Q point C (cervix), point D (posterior fornix), point Ba (maximum descent of the anterior compartment) and Tvl (total vaginal length) as well as mean changes in patientreported POP-related symptoms and sexual distress. POPrelated symptoms were evaluated in several ways. The women were asked at the time of follow-up to self-evaluate their results using a question on subjective cure for POP, scaled from 1 (= worse) to 4 (= completely cured). Furthermore, we used the changes in total PFDI-20 score, domain scores of POP Distress (POPDI-6) and Urinary Distress (UDI-6) and the single question: "Do you usually have a bulge or something falling out that you can see or feel in your vaginal area?" (Question 3, POPDI-6). Changes in sexual distress were evaluated by mean change in PISQ-12 scores as well as the single question: "Do you feel pain during sexual intercourse?" (Question 5, PISQ-12). To evaluate the incidence of de novo dyspareunia, a score of the latter of 3 (usually) or 4 (always) was considered dyspareunia. Missing items were accounted for according to the original descriptions of the questionnaires. [16, 17].

Statistical analysis was performed using SPSS version 24. Paired samples t-test was used to compare means and Pearson's correlation used to analyze bivariate correlations between anatomic changes in the anterior compartment (Ba) and mid-compartment (C) with the above POP-related and sexual symptom scores.

Sample size was estimated for paired data and based on expected proportions. We assumed that 85% of the patients would achieve a POP-Q point $C \le -5$ based on unpublished data from our internal quality registry where 85% of the women operated on for POP between 2002 and 2005 were registered at 1-year follow-up with stage 0 in the mid-compartment (equivalent to point $C \le -5$). With a power of 80% and a significance level of 0.05, from the statistical table for paired data the estimated number of patients needed was 138 [20]. As we expected some postponed/canceled surgeries, loss to follow-up, etc., our inclusion aim was 160 women.

Results

Originally, 160 women scheduled for MP were included, of whom 7 ended up not being operated on with MP for various reasons. Thus, the final data set consisted of 153 women. Five were lost to 1-year follow-up; thus, the final analyses were performed on 148 women (Fig. 2). Mean age at time of surgery was 61.6 years [standard deviation (SD) \pm 11.4], mean BMI was 24.8 (SD ± 3.6), 8 patients (5.4%) had chronic diseases affecting the bladder, bowel or lung (potentially causing increased intraabdominal pressure), 14.9% had previously had a laparoscopy, 19.6% had previously had a laparotomy, and 4.7% had undergone both procedures. At time of inclusion, 86.0% were postmenopausal, of whom 9.5% used systemic hormonal treatment, whereas 53.2% only used vaginal estrogens. Median parity was 2 (range 0–7). Three patients were nulliparous, and the remaining women (98.0%) had given birth vaginally at least once, 5.5% of whom had also undergone a cesarean section. Eligible women not included (n = 22; of whom 7 denied inclusion, see Fig. 2) and women not included because of insufficient fluency in Scandinavian/English (n = 10) (Fig. 2) were similar to the study participants in age and POP stage, but had significantly higher BMI (p = 0.02).

Ninety-seven percent attended the 1-year follow-up (148/ 153). Median time to follow-up was 12 months (range 8–16). POP-Q points (Ba, Bp, C, D, gh, pb and tvl) were nearnormally distributed. Pre- and postoperative POPQ points and stages are presented in Table 1. At the 1-year follow-up, POP-Q stage 0–1 was present in 99.3% (n = 147) in the midcompartment, but only in 48.6% (n = 72) in the anterior compartment. Of the 47.3% (n = 70) who had stage 2 in the anterior compartment, 81.4% (57/70) had point Ba at or above the hymenal plane. Point C ≤ -5 (equivalent to stage 0) was present in 81.1% (120/148). Since our sample size estimation was based on an expected proportion of 85% with C ≤ -5 , a post hoc study power calculation was performed using a paired ttest for changes in C, which confirmed an adequate sample size (n = 101 for effect size 0.81 and SD of change 2.9).

Patient-reported outcomes are presented in Table 2. Ninetysix percent reported being cured or their POP symptoms had improved. Significant symptom reduction was reported in all POP-related and sexual symptom scores (p < 0.05), except for dyspareunia (p = 0.70). Pre- and postoperative dyspareunia is described in Fig. 3. De novo dyspareunia was reported in 4/72 women (5.6%). In addition, one of the women who had been sexually inactive prior to the operation (and thus no information existed on preoperative dyspareunia) reported dyspareunia postoperatively.

Only 1 of the 148 women underwent repeat POP surgery because of recurrence within the first year of follow-up (0.7%; 1/148).

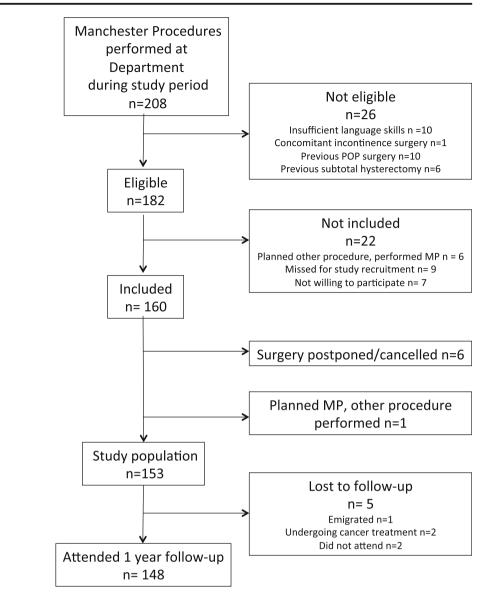
By dichotomizing women with postoperative anterior compartment POP stage 2 into Ba above/below the hymenal plane, we found a trend toward increased postoperative symptoms of bulging in the latter group (p = 0.08). Not surprisingly, anatomical changes in the anterior compartment (Ba) correlated significantly with changes in C and D (p = 0.01). Furthermore, anatomical changes in the anterior compartment were significantly correlated with POP-specific symptoms (POPDI-6, p = 0.01), urinary distress symptoms (UDI-6, p < 0.01) and symptoms of bulging (q.3, POPDI-6, p < 0.01). In other words, women with the best anatomical reduction of the anterior wall descent seemed to have less POP-related distress symptoms 1 year after surgery. No significant correlations were demonstrated between changes in the midcompartment (C) and changes in PFDI-20 scores (total or subdomains) except for the single symptom of bulging (q.3, POPDI-6, p = 0.04). The changes in the anterior or midcompartment measurements did not correlate significantly with changes in sexual distress (PISQ 12) or dyspareunia (q.5, PISQ-12).

Postoperative complications are presented in Table 3. The overall complication rate was 11.8% (n = 18), with hematomas and prolonged postoperative pain as the main problems. Surgical re-interventions due to complications were performed in six patients (3.9%).

Fig. 2 Inclusion and follow-up,

women operated on by the

Manchester procedure



Discussion

This study is to our knowledge one of the very few prospective studies evaluating the Manchester procedure. We were able to demonstrate that the procedure gives adequate apical elevation, in accordance with recent publications comparing MP with vaginal hysterectomy [21, 22]. Ideally, points C and D become equal after MP. The anatomical improvement in the midcompartment cannot be explained solely by the cervical amputation, since a significant elevation was also achieved in point D (posterior fornix). We believe the main cause of the apical point (D) elevation was the shortening and repositioning of the uterosacral and cardinal ligaments (US/CL), as these ligaments are known to contain both elastin and smooth muscle fibers [23]. Although this step is crucial in the original description of the MP [14], we suspect that it is often neglected during surgery. Even though the few early studies evaluating the procedure demonstrated good outcomes [24], the procedure was abandoned in many urogynecologic units for reasons unknown and for the last decade replaced with transvaginal mesh procedures.

POP symptoms are often described as correlating poorly with anatomy [22]. However, in the present study, we found a trend toward decreased symptom scores of bulging in women with postoperative stage 2, where Ba was at or above the hymenal level (81% of women with stage 2) compared with those with Ba below the hymenal plane (p = 0.08). This may support the hymenal level as a natural threshold for symptomatic anterior compartment prolapse, as previously proposed by others [25].

In our study, changes in Ba correlated with both a reduction in prolapse symptoms and urinary distress, but more surprisingly changes in C also correlated significantly with a reduction of the symptom of bulging. This again adds to the importance of mid-compartment elevation in women with a predominant anterior compartment prolapse. As demonstrated

Table 1 Anatomical outcomesbefore and 1 year after theManchester procedure $(n = 148)^1$

POP-Q measurements	Preoperative	Postoperative	Paired differences [mean (SD ²) cm]	р
Anterior compartment				
Point Ba ³ (mean (SD) cm)	+ 1.8 (± 1.7)	- 1.1 (± 1.4)	$-2.9 (\pm 1.8)$	< 0.01
Stage 0-I [% (n)]	2.0 (n=3)	48.6 (<i>n</i> = 72)		
Stage II [% (n)]	41.9 (<i>n</i> = 62)	47.3 $(n = 70)$		
Stage III [% (n)] Posterior compartment	56.1 (<i>n</i> = 83)	4.1 (n=6)		
Point Bp ⁴ [mean (SD) cm]	-1.1 (± 1.4)	$-2.8 (\pm 0.6)$	$-1.7 (\pm 1.4)$	< 0.01
Stage 0–I [% (n)]	52.0 (n = 77)	98.0 (<i>n</i> = 145)		
Stage II [% (n)]	41.2 (n = 61)	2.0 (n=3)		
Stage III [% (n)] Mid-compartment	6.8 $(n = 10)$	0.0 (n=0)		
Point C ⁵ [mean (SD) cm]	-1.2 (± 2.8)	-5.9 (± 1.7)	- 4.8 (±2.9)	< 0.01
Mean point D ⁶ (cm)	-6.4 (± 1.5)	-7.0 (± 1.2)	$-0.7 (\pm 2.0)$	< 0.01
Stage 0–I [% (n)]	$50.0 \ (n = 74)$	99.3 (<i>n</i> = 147)		
Stage II [% (n)]	31.8 $(n = 47)$	0.0 (n=0)		
Stage III [% (n)] Other POPQ measurements	17.6 (<i>n</i> = 26)	0.7 (n = 1)		
Tvl ⁷ [mean (SD) cm]	8.2 (± 1.2)	7.9 (± 1.1)	$-0.3 (\pm 2.2)$	0.03
Gh ⁸ [mean (SD) cm]	4.6 (± 1.1)	3.4 (± 0.8)	$-1.2 (\pm 1.1)$	< 0.01
Pb ⁹ [mean (SD) cm]	2.5 (± 1.2)	3.6 (± 1.0)	1.1 (± 1.5)	< 0.01

¹ No women had pre- or postoperative stage IV in any compartment. ² Standard deviation. ³ Max. desc. ant.comp. ⁴ Max. desc. post. comp. ⁵ Max desc. cervix. ⁶ Max desc. post fornix. ⁷ Total vaginal length. ⁸ Genital hiatus. ⁹ Perineal body

by others, we found that the MP does not fully restore the anterior compartment. However, reducing the anterior prolapse proximal to the level of the hymen has also been shown by others to significantly lower POP symptoms and have a clear correlation with patient satisfaction [25]. The overall complication rate in our study cohort was 11.8%. This is within the expected rates for the MP [12] and other mid-compartment procedures [26]. It is also far lower than what has been reported for anterior compartment surgery using synthetic mesh [27]. Even though cervical stenosis has

 Table 2
 Patient-reported outcomes 1 year after Manchester procedures (n = 148)

			Cured/ improved		Unchanged		Worsened	
			n/Na	%	n/Na	%	n/Na	%
Subjective results (scaled 0–4):			142/148	96.0b	5/148	3.4	1/148	0.7
Changes in symptom scores:	Mean paired differences (SD)	Р						
Pelvic floor distress (PFDI-20)	-54.12 (47.00)	< 0.01	132/147	89.8	0/145	0.0	15/147	10.2
POP symptoms (POPDI-6)	-33.3 (24.21)	< 0.01	134/147	91.2	4/147	2.7	9/147	6.1
"Bulging"(q.3, PFDI-20)	-2.45 (1.64)	< 0.01	117/144	81.3	23/144	16.0	4/144	2.8
Urinary distress (UDI-6)	-15.52 (23.04)	< 0.01	105/147	71.4	13/147	8.8	29/147	19.7
Stress urinary incontinence (q.17, PFDI-20)	-0.35 (1.31)	< 0.01	35/144	24.3	94/144	65.3	15/144	10.4
Urgency urinary incontinence (q.16, PFDI-20)	-0.38 (1.6)	< 0.01	47/145	32.4	74/145	51.0	24/145	16.6
Incomplete bladder emptying (q.19, PFDI-20)	-1.08 (1.58)	< 0.01	71/145	49.0	64/145	44.1	10/145	6.9
Sexual dysfunction (PISQ-12)	-1.60 (5.00)	0.01	33/64	51.6	8/64	12.5	23/64	35.9
Dyspareunia (q.5, PISQ-12)	0.05 (1.12)	0.70	16/65	24.6	32/65	49.2	17/65	26.2

^aN differs because of missing/incomplete answers

^b Cured: 70.3% (n = 104); improved: 25.7% (n = 38)

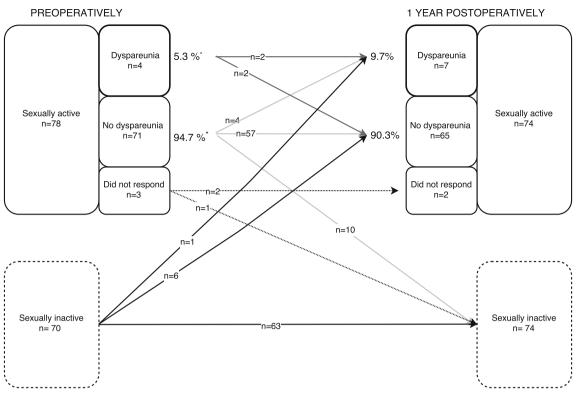


Fig. 3 Pre- and postoperative dyspareunia, women operated on with MP (n = 148)

been reported in the literature as a main risk after an MP, especially in postmenopausal women [28], we only identified this in one woman in our patient cohort.

In recent publications, the term Manchester procedure has often been used without including a reconstruction of the perineal body [12], possibly omitted to avoid causing dyspareunia. Although still controversial, in our opinion, when an MP is performed for anterior compartment repair, a reconstruction of the perineal body will prevent symptomatic recurrence, as this perineal body repair procedure restores the floor on which the anterior wall rests during strain. The effect of the MP on dyspareunia is difficult to evaluate. Analyzing the question in the PISQ-12 questionnaire specifically

 Table 3
 Postoperative complications, Manchester procedures (n = 153)

	n	Percent
Ureteric kink/injury	1	0.7
Minor bleeding/hematoma	5	3.3
Profuse bleeding ^b	2	1.3
Prolonged postoperative painc	6	3.9
Minor infection	3	2.0
Cervical stenosis	1	0.7
Total complications	18	11.8a

^a Percentages do not add up because of rounded values. ^b In need of transfusion

^c More than 4-week duration

targeting dyspareunia, no significant change was found 1 year after MP (p = 0.70, Table 2). De novo dyspareunia was found in 5.6% of the sexually active women, whereas one woman, who became sexually active after surgery, also reported dyspareunia. However, four women in the cohort reported preexisting dyspareunia, half of whom improved. All of the above implies that this is a population (mainly postmenopausal) in which the individual impact of surgery is difficult to predict. However, overall sexual function as indicated by the PISQ-12 scores demonstrated an overall improvement after the MP (p = 0.01). We still believe it is important when performing surgery in the posterior compartment that care is taken to avoid including deeper muscular layers (m. levator ani) in sexually active women.

The strength of the present study is the large sample size and prospective design. To our knowledge, to date only two studies have been published relatively recently on MP with a prospective design [21, 22]. Both of these studies compared the MP with vaginal hysterectomy (VH).

As this is a single-center study, all surgeons attempted to perform the surgeries in a similar manner. Furthermore, residents were always assisted by experienced urogynecologists when performing these MP surgeries. However, there are some weaknesses in the study design, one being the short follow-up time (only 1 year). We are, however, planning a 5year follow-up of the cohort. It might also be considered a weakness that the length of the amputated cervix was not measured before surgery, so the degree of apical change solely attributed to US/CL suspension could have been evaluated. The surgeons were not allowed to assess their own patients at the 1-year follow-up, and the doctor evaluating the women was blinded to most of the preoperative study information (such as exact preoperative POP-O measurements and answers to PISQ-12/PFDI-20). However, the postoperative evaluators had access to information in the medical charts (such as preoperative prolapse staging). Even though this theoretically could introduce bias when evaluating the results, we believe the risk of a significant impact on the results is negligible. Some might claim that our results from uterus-sparing surgery are not necessarily applicable to other populations where hysterectomy rates for benign indications are substantially higher. However, in recent years, hysterectomy rates for benign causes have decreased worldwide, including in the US [29]. We believe uterus-sparing POP surgery will retain its place also in future POP surgery, especially since the risk of vault prolapse is known to be substantially higher after uterus removal [30].

In conclusion, this study shows that the MP provides adequate mid-compartment support and excellent subjective outcomes at 1-year follow-up, whereas the less optimal anatomical outcomes in the anterior compartment may be still be considered a challenge. The obtained anatomical changes in the mid-compartment correlated well with the changes in the sole symptom of bulging, whereas the anatomical changes in the anterior compartment also correlated with the overall changes in POP symptoms and urinary distress. The inferior anatomical outcome in the anterior compartment did not seem to affect subjective satisfaction, implying that the aim of surgery in the anterior compartment should be to reduce the prolapse to above the level of the hymen, not necessarily aiming for stage 0–1. In addition, the perineal body restoration might have reduced the potential negative subjective effects of a less optimal anatomical anterior wall repair.

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Compliance with ethical standards

Conflicts of interest None.

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