

# Native-tissue repair of isolated primary rectocele compared with nonabsorbable mesh: patient-reported outcomes

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## Abstract

**Introduction** We evaluated patient-reported outcomes and complications after treatment of isolated primary rectocele in routine health-care settings using native-tissue repair or non-absorbable mesh.

**Methods** We used prospective data from the Swedish National Register for Gynaecological Surgery and included 3988 women with a primary operation for rectocele between 2006 and 2014: 3908 women had native-tissue repair, 80 were operated with nonabsorbable mesh. No concurrent operations were performed. Pre- and perioperative data were collected from doctors and patients. Patient-reported outcomes were evaluated 2 and 12 months after the operation. Only validated questionnaires were used.

**Results** One year after native-tissue repair, 77.8 % (76.4–79.6) felt they were cured, which was defined as never or hardly ever feeling genital protrusion; 74.0 % (72.2–75.7) were very satisfied or satisfied, and 84 % (82.8–85.9) reported improvement of symptoms. After mesh repair, 89.8 % (77.8–96.6) felt cured, 69.2 % (54.9–81.3) were very satisfied or satisfied, and 86.0 % (72.1–94.7) felt improvement. No significant differences were found between groups. Organ damage was found in 16 (0.4 %) patients in the native-tissue repair

group compared with one (1.3 %) patient in the mesh group [odds ratio (OR) 3.08; 95 % confidence interval (CI) 0.07–20.30]. The rate of de novo dyspareunia after native-tissue repair was 33.1 % (30.4–35.8), comparable with that after mesh repair. The reoperation rate was 1.1 % (0.8–1.5) in both groups.

**Conclusion** Most patients were cured and satisfied after native-tissue repair of the posterior vaginal wall, and the patient-reported outcomes were comparable with results after mesh repair. The risk of serious complications and reoperation were comparable between groups.

**Keywords** Colporrhaphy · National register data · Non absorbable mesh · Patient-reported outcome · Rectocele

## Introduction

Pelvic organ prolapse (POP) is a common condition, affecting up to 50 % of parous women [1]. Lifetime risk of undergoing surgical intervention for POP is estimated to be between 6.3 % and 19 %. Due to complications, recurrence, or de novo prolapse, approximately 10–30 % of these women have subsequent prolapse surgery [2]. Rectocele is the second most common type of POP, and the Incidence of rectocele is 5.7 cases per 100 women-years [1]. Treatment of POP is controversial, and over time, professionals have tried to find the optimal care of the different types of POP using both surgical and nonsurgical methods. Since the 1990s, the benefit of mesh in POP operations has been investigated, but no clear conclusion has yet been reached. The use of mesh in prolapse surgery may lower the risk of recurrence of symptoms but also includes a potential risk of mesh-related complications [1]. The most common of these complications is mesh erosion [3], the rate of which ranges from 1 to 17 % after vaginal mesh operations

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[1]. Even though it might be asymptomatic, mesh erosion accounts for many of the reoperations necessary after prolapse surgery [4]. Pain and dyspareunia are other mesh-related complaints, but these are also well-known complications following native-tissue repair [5]. The literature is inconclusive regarding the rates of these complications and which surgical technique carries the lowest risk [6]. Patients' own evaluation of treatment results is of great importance, and patient-reported outcome measures (PROMs) have been developed and used increasingly to assess treatment results [7, 8]. However, the literature lacks information on patient-reported outcomes in large cohorts of patients operated for rectocele.

The aim of this study was to describe and compare patient-reported outcomes and complications for low-risk patients after repair of primary rectocele in routine care settings using either native-tissue repair or nonabsorbable mesh.

## Materials and methods

This is a prospective, register-based cohort study of 3988 patients operated for isolated primary rectocele from 1 January 2006 to 31 December 2014 in Sweden. All patients were operated with native-tissue repair ( $n = 3908$ ) or with implantation of a nonabsorbable, polypropylene mesh ( $n = 80$ ). Of these, 52 % were Prolift® meshes and 48 % were various brands of type 1 polypropylene meshes. Native-tissue repair comprised either site-specific repair, midline placcation, or levator plasty. Only healthy patients were included in the study [American Society of Anesthesiologists (ASA) preoperative physical status classification system group one or two]. Patients operated with absorbable/biological mesh were excluded, as were patients with additional anterior and/or apical defects needing operation. Data was collected prospectively by the Swedish National Register for Gynaecological Surgery [9] (GynOp, [www.gynop.org](http://www.gynop.org)) using Internet and paper-based questionnaires. Patients were included in the register at the preoperative consultation. They could refuse participation, but no consent form was needed according to Swedish law. GynOp registers >95 % of all gynecological operations conducted in Sweden.

Preoperatively, patients completed a health declaration form and a validated questionnaire about their general health condition and questions focusing on gynecological symptoms, especially prolapse symptoms [10]. The gynecologist completed a form on preoperative objective findings, an operation form at the time of surgery with detailed information about technique and materials, and a postoperative form at discharge. Two and 12 months postoperatively, all patients filled in a validated questionnaire concerning well-being and treatment-related complications (GynOp 8-week and 1-year questionnaires) [11]. Patient-reported improvement was reported on a scale from very improved, improved, no change,

worsened, or much worsened. Furthermore, patients were asked if they were very satisfied, satisfied, no change, unsatisfied, or very unsatisfied with result of the operation. The operating gynecologist received this questionnaire and added an evaluation of the patient's answer. If patients had complaints after 2 or 12 months, they were called for a clinical examination. Patient questionnaires and surgeon evaluations were reported to the register. The data-collection process has previously been described in further detail, including a description of the questionnaires used [8, 9].

Results reported here are based on the 12-month follow-up. Cure was defined as never or hardly ever feeling genital protrusion. Patients were considered satisfied if they answered very satisfied or satisfied when evaluating satisfaction. Similarly, they were considered improved if they answered very improved or improved when evaluating improvement. Missing data represent patients who did not answer an individual question. Information of missing data is presented in the tables.

## Statistical analysis

We used the chi-square test for analyses of categorical data, and the *t* test and Mann–Whitney *U* test for continuous data. Proportions are presented with 95 % exact confidence intervals (CI). Multiple logistic regression models were constructed to examine the association between type of operation and each outcome. Risks are presented as unadjusted and adjusted odds ratios (OR) with 95 % CI. As potential confounders, we included age (continuous), preoperative use of estrogen (yes/no), degree of prolapse (stage 0–4) [12], and number of primary rectocele operations in each unit per year ( $\geq 100$ / $< 100$ ). No attempt was made to correct for multiple testing, as most methods tend to yield conservative estimates, which in the case of risk of complications would be to err in the wrong direction.

Despite the huge participation rate in the overall database, data was missing for specific outcomes and covariates, ranging from 0 for most complications to >2500 for specific patient-reported outcomes such as dyspareunia. For patient satisfaction and improvement, and to assess de novo dyspareunia, we performed relevant sensitivity analyses, assuming in turn that all women with missing information either: (1) did not experience de novo dyspareunia, or (2) had the same risk as those with an implant. SPSS, version 20.0, and Stata 12 (StataCorp LP, College Station, TX, USA), were used for data analysis.

## Ethics

The Ethics Committee, University of Umeå, Sweden, approved The Swedish National Register for Gynaecological

Surgery (Dnr 04–107) and the study (08–076 M). All women were informed that they could decline to be registered.

## Results

Demographic data of all 3988 participants are given in Table 1. Women in the mesh group were significantly older than those in the native-tissue group: mean 67 vs 59 years, respectively ( $p < 0.01$ ).

Women in the mesh group had a significantly larger degree of prolapse than women in the native-tissue group ( $p < 0.001$ ), and more women in the mesh group used estrogen before the operation ( $p = 0.021$ ). There was no significant difference in body mass index (BMI), parity, and smoking habits. There was also no significant difference in operation methods between departments with a low or high volume of operations (Table 1).

## Patient-reported outcomes

One year after native-tissue repair, the patient-reported cure rate was 77.8 % (76.4–79.6) and 89.8 % (77.8–96.6) after mesh repair, with no significant difference. Of women operated using native-tissue repair, 74.0 % (72.2–75.7) were very satisfied or satisfied and 84.4 % (82.8–85.9) felt improvement, whereas in the mesh group, 69.2 % (54.9–81.3) were satisfied and 86.0 % (72.1–94.7) felt improvement, also with no significant difference (Table 2).

No differences were found in patient-reported complications within the first 8 weeks after the operation (Table 2). Patient-reported complications from 8 weeks to 1 year showed a significant difference, with more complications needing medical attention in the native-tissue group. Patients in the native-tissue group needed painkillers after discharge for a significantly shorter duration (mean 6.4 days) compared with the mesh group (mean 8.9 days) ( $p = 0.006$ ). We found no significant difference between groups with respect to voiding

**Table 1** Descriptives of participants with posterior vaginal wall prolapse repaired using native tissue or mesh

	Implant ( $n = 80$ )		No implant ( $n = 3908$ )		$P$ value
Mean age, years (SD)	67.1 (10.0)		59.0 (12.6)		<0.001
Patient questionnaires					
BMI					
Mean (SD)	27.4 (3.6)		26.6 (4.1)		0.084
Parity					
0–2	42	(52.5)	1900	(48.6)	0.114
3+	35	(43.8)	1574	(40.3)	
Missing	3	(3.8)	434	(11.1)	
Smoking					
Yes	10	(12.5)	371	(9.5)	0.120
No	67	(83.8)	3131	(80.1)	
Missing	3	(3.8)	406	(10.4)	
Preoperative estrogen					
Yes	37	(46.3)	1406	(36.0)	0.021
No	37	(46.3)	1765	(45.2)	
Missing	6	(7.5)	737	(18.9)	
Sugeron-completed forms					
Leading edge of the posterior vaginal wall in relation to the hymen (cm); median (range)	+2 (–3.8)		+1 (–3.8)		<0.001
Missing ( $n$ )	24		1094		
Stage of prolapse <sup>a</sup>					
0 (–3 cm)	2	(2.5)	61	(1.6)	<0.001
1 (> –3; < –1)	0	(0.0)	163	(4.2)	
2 ( $\geq -1$ ; $\leq 1$ )	25	(31.3)	1927	(49.3)	
3/4 (>1)	29	(36.3)	663	(17.0)	
Missing	24	(30.0)	1094	(28.0)	
Large departments ( $\geq 100$ operations/year)	49	(61.3)	2311	(59.1)	
Small departments (<100 operations/year)	31	(38.8)	1597	(38.8)	

Missing patients who did not answer this question,  $SD$  standard deviation,  $BMI$  body mass index

<sup>a</sup> Degree of prolapse (+/– cm from hymen)

**Table 2** Posterior vaginal wall prolapse repaired using native tissue or mesh

Patient-reported outcomes								
Native tissue or mesh	Missing ( <i>n</i> )	No.	Yes ( <i>n</i> )	RD	OR <sup>a</sup>	95 % CI	OR <sup>b</sup>	95 % CI
Awareness of a vaginal bulge or protrusion 1 year								
No implant	1408	2500	555		1		1	
Implant	31	49	5	-0.120	0.40	(0.16–1.01)	0.48	(0.19–1.22)
Satisfaction: 1 year								
No implant	1352	2556	1891		1		1	
Implant	28	52	36	-0.048	0.79	(0.44–1.44)	0.68	(0.37–1.25)
Improvement: 1 year								
No implant	1648	2260	1907		1		1	
Implant	37	43	37	0.0167	1.14	(0.48–2.73)	1.07	(0.44–2.57)
Complications within 8 weeks requiring medical attention								
No implant	650	3258	769		1		1	
Implant	12	68	12	-0.060	0.70	(0.37–1.30)	0.75	(0.40–1.42)
Complications after 8 weeks and within 1 year requiring medical attention (only patients not previously reported)								
No implant	3003	905	528		1		1	
Implant	56	24	8	-0.250	0.36	(0.15–0.84)	0.41	(0.17–0.97)
Complications needing hospitalization within 8 weeks								
No implant	3083	825	133		1		1	
Implant	64	16	1	-0.099	0.35	(0.05–2.65)	0.29	(0.04–2.22)
Urinary infection postoperatively								
No implant	318	3590	175		1		1	
Implant	6	74	5	0.019	1.41	(0.56–3.55)	1.11	(0.44–2.82)

Missing patients who did not answer this question, No. patients who answered this question, RD risk difference:  $CI_{\text{mesh}} - CI_{\text{native tissue}}$  (CI = incidence), OR odds ratio, CI confidence interval

<sup>a</sup> Unadjusted

<sup>b</sup> Adjusted for age, preoperative estrogen, degree of prolapse, and number of primary operations in unit

pain extending 1 month postoperatively and pain in the loin within 8 weeks (Table 2).

Frequency of sexual intercourse was not significantly affected by type of surgery: 8.1 % (7.0–9.3) of patients reported increased frequency, whereas 5.6 % (4.7–6.7) reported reduced frequency. In the native-tissue group, de novo dyspareunia was reported by 33.1 % (30.4–35.8) of patients, improved dyspareunia by 20.5 % (18.0–23.1), and 12.5 % (10.4–14.8) reported worsened dyspareunia, with no significant difference between groups. When asked about bowel-emptying problems, patients reported conflicting outcomes: significantly more women in the mesh group reported both improvement in bowel function and worsened bowel function (Table 3).

### Surgeon-reported outcomes

We found no significant difference in doctor-reported complications or number of reoperations within 12 month between groups: 17.0 % (15.8–18.2) had complications within 12 months after native-tissue repair and 22.5 % (13.9–33.2)

after mesh repair. Reoperation due to complications or recurrence was conducted in 1.1 % (0.8–1.5) of patients in both groups within 12 months (Tables 4 and 5).

In both groups, women achieved activities of daily living (ADL) in a median of 3 days ( $p = 0.59$ ) (Table 6).

### Organ damage and fistulas

After native-tissue repair, peroperative organ damage was found in 16 patients: one patient experienced damage in two organs (12 with intestinal damage, four with wound dehiscence, and one with bladder injury). In the mesh group, one patient had intestinal injury. After native-tissue repair, the risk of organ damage was 0.4 % compared with 1.3 % after mesh repair (OR 3.08, 95 % CI 0.07–20.30). No cases with fistulas were found in the cohort.

### Resource outcomes

Estimated hemorrhage during operation was statistically significantly higher in the native-tissue group (mean 39.8 ml)

**Table 3** Patient-reported functional parameters 1 year after surgery: posterior vaginal wall prolapse repaired using native-tissue or mesh

Functional Parameters								
Native tissue or mesh	Missing ( <i>n</i> )	No.	Yes ( <i>n</i> )	RD	OR <sup>a*</sup>	95 % CI	OR <sup>b</sup>	95 % CI
Increased frequency of sexual intercourse <sup>c</sup>								
No implant	1723	2185	176		1		1	
Implant	31	49	4	0.001	1.02	(0.36–2.85)	1.10	(0.39–3.14)
Reduced frequency of sexual intercourse <sup>c</sup>								
No implant	1778	2130	121		1		1	
Implant	34	46	1	−0.035	0.37	(0.05–2.70)	0.36	(0.05–2.65)
Dyspareunia: improved or symptom free <sup>c</sup>								
No implant	2893	1015	208		1		1	
Implant	62	18	1	−0.149	0.23	(0.03–1.73)	0.31	(0.04–2.40)
Dyspareunia: worsened <sup>c</sup>								
No implant	2986	922	115		1		1	
Implant	62	18	1	−0.069	0.41	(0.05–3.13)	0.56	(0.07–4.34)
Dyspareunia: de novo <sup>c</sup>								
No implant	2702	1206	399		1		1	
Implant	61	19	2	−0.564	0.24	(0.06–1.04)	0.28	(0.06–1.25)
Bowel-emptying problems: improved <sup>c</sup>								
No implant	1708	2200	1392		1		1	
Implant	31	49	23	−0.163	0.51	(0.29–0.91)	0.55	(0.31–0.98)
Bowel-emptying problems: worsened <sup>c</sup>								
No implant	2800	1108	300		1		1	
Implant	52	28	2	−0.199	0.21	(0.05–0.88)	0.22	(0.05–0.92)
Bowel emptying problems: de novo <sup>c</sup>								
No implant	2956	952	144		1		1	
Implant	49	31	5	0.010	1.08	(0.41–2.86)	1.00	(0.37–2.73)

Missing patients who did not answer this question, *No.* patients who answered this question, *RD* risk difference =  $CI_{\text{mesh}} - CI_{\text{native tissue}}$  (*CI* = incidence), *OR* odds ratio, *CI* confidence interval

<sup>a</sup> Unadjusted

<sup>b</sup> Adjusted for age, preoperative estrogen, degree of prolapse, and number of primary operations in unit

<sup>c</sup> Compared with no change

compared with the mesh group (mean 35.6 ml). Operating time was shorter in the native-tissue group (mean 43.9 min) compared with the mesh group (mean 48.8 min). Moreover, time in hospital was significantly shorter in the native-tissue-group compared with the mesh group.

### Sensitivity analyses

If all women with missing information regarding cure rate had the same cure rate as those with valid information, the reduction in risk of vaginal bulge/protrusion would have been significant (OR 0.39 (95 % CI 0.16–0.81) in favor of native-tissue repair. The risk of de novo dyspareunia would have been reduced from 33.1 % among women without implant to 10.2 % (95 % CI 9.3–11.2) assuming that all women with missing information did not have de novo dyspareunia and to 17.5 % (95 % CI 16.3–18.7) assuming that women with

missing information had the same risk as those with an implant. The risk estimates (OR) for patient satisfaction, improvement, and dyspareunia, which were all insignificant in the main analyses, were further attenuated in the sensitivity analyses.

### Discussion

This large database study demonstrates that most women with primary isolated rectocele are cured, satisfied, and improved after native-tissue repair and that these results are comparable with mesh repair. No clinically relevant differences in complication rates were found between groups. The literature on rectocele repair is sparse, and the majority of studies are small and inhomogeneous [1]. Our study cohort is—to our knowledge—the largest on a homogeneous group of patients

**Table 4** Surgeon-reported parameters: posterior vaginal wall prolapse repair using native-tissue or mesh

Resource Parameters							
Native tissue or mesh	Missing ( <i>n</i> )	No.	Mean	SD	Median	Min–max	<i>P</i> -+ value
Operation time (min)							
No implant	17	3291	43.9	18.3	40.0	11–160	0.019
Implant	4	76	48.8	19.6	45.0	20–110	
Time in hospital (days)							
No implant	129	3779	0.6	0.8	0.0	0–10	<0.001
Implant	3	77	1.1	1.2	1.0	0–6	
Hemorrhage during operation (ml)							
No implant	619	3289	39.8	30.1	30.0	0–150	0.006
Implant	6	74	35.6	42.6	25.0	0–700	–

*Missing* patients who did not answer this question, *No.* patients who answered this question, *SD* standard deviation

*RD* risk difference:  $CI_{\text{mesh}} - CI_{\text{native tissue}}$  (*CI* = incidence), *OR* odds ratio, *CI* confidence interval

<sup>a</sup> Unadjusted

<sup>b</sup> Adjusted for age, preoperative estrogen, degree of prolapse, and number of primary operations in unit

operated for primary rectocele, involving 3988 patients operated in standard medical settings. The Swedish National Database using validated questionnaires for subjective patient-reported data collected all data prospectively: 75 % of Swedish gynecological departments report to the database, and these departments reported 98 % of their patients. Data completeness is validated annually, and data are randomly checked with medical records as a reference. The general participation rate is high: approximately 95 % initially and 85 % complete the 1-year follow-up [8]. Patient-reported outcomes are collected and correlated with doctor-reported findings. Thus, this study was based on highly reliable data from the Swedish database and describes outcomes in standard-care settings. Only 2 % of patients in this study were operated with mesh insertion, reflecting a very conservative attitude in the Nordic countries, where mesh almost exclusively has been used in operations for recurrent prolapse. This study supports this attitude, since no benefits are shown when using mesh repair on primary rectocele patients.

Formerly, the success of operative treatment of POP was based on objective findings [13], and previous studies on rectocele treatment have only very sparse information on patient satisfaction [1]. Many women develop some degree of prolapse with age, but not all women have symptoms. Accordingly, new recommendations on reporting outcomes of POP surgery include both objective findings, patient-reported outcomes and satisfaction, quality of life, and perioperative data [14]. The lack of objective data in this study might be criticized. However, since only women having symptoms of prolapse need surgical treatment, patient-reported outcome might be the most important parameter. Patient-reported outcomes in this study demonstrate a very high cure rate and satisfaction after native-tissue repair, with no further benefit of mesh implant.

The use of mesh—either synthetic or biological—was introduced to minimize recurrence after primary prolapse surgery. Traditionally, randomized controlled trials (RCT) are considered to give the highest degree of evidence when

**Table 5** Medical complications

Native tissue or mesh	Missing	Data present ( <i>n</i> )	No. cases	RD	OR <sup>a*</sup>	95 % CI	OR <sup>b</sup>	95 % CI
Doctor-reported complication within 12 months								
No implant	0	3908	663	–	1	–	1	–
Implant	0	80	18	0.055	1.42	0.84–2.42	1.47	0.86–2.51
Reoperation within 12 months								
No implant	0	3908	44	–	1	–	1	–
Implant	0	80	1	0.001	1.11	0.15–8.17	1.22	0.16–9.12

*RD* risk difference:  $CI_{\text{mesh}} - CI_{\text{native tissue}}$  (*CI* = incidence), *OR* odds ratio, *CI* confidence interval

<sup>a</sup> Unadjusted

<sup>b</sup> Adjusted for age, preoperative estrogen, degree of prolapse, and number of primary operations in unit



**Table 6** Days achieving activities of daily living

Native tissue or mesh	Missing ( <i>n</i> )	No.	Mean	SD	Median	Min–max	<i>P</i> value
No implant	1272	2636	4.6	4.7	3.0	0–21	0.585
Implant	23	57	4.0	3.7	3.0	0–14	

*SD* standard deviation

comparing different operative procedures, because confounding can be eliminated. No RCTs have investigated the use of synthetic mesh in isolated posterior vaginal wall repair. Only one RCT exclusively studied rectocele surgery [15], but the mesh used was biological. In that study, porcine graft resulted in worse anatomic outcome compared with native-tissue repair, but overall improvement was high, and no significant difference in improvement was found between groups. Another RCT investigated an inhomogeneous group of 184 women with POP randomized for either native-tissue or mesh repair; of those women, only 16 had isolated rectocele. Concomitant procedures included both hysterectomy and transvaginal tape (TVT) insertion when indicated [16]. Data showed a greater success in the mesh group when evaluated both objectively and subjectively. However, there was a mesh exposure rate of 20 %. An RCT with 3-years' follow-up assessed 65 women who had prolapse surgery in either compartment with or without synthetic mesh and combined with hysterectomy if the uterus was present [17, 3, 18]. The trial was stopped prematurely as a result of a 15.6 % mesh exposure rate. After 3-years' follow-up no significant difference in cure rate and sexual function was found between the mesh and no-mesh groups. Also a large recurrence rate on 66.2 % was found, with no difference between groups. An RCT involving 139 women who received combined anterior and posterior colporrhaphy with or without synthetic mesh failed to demonstrate that vaginal repair surgery with mesh was significantly more successful in terms of reduced recurrence [19]. No significant difference in dyspareunia was found between the groups. Thus, data from RCTs concerning isolated rectocele are very sparse, and the advantage of using mesh in the posterior compartment has not yet been proven.

The use of mesh—either synthetic or biological—was developed to minimize recurrence after primary prolapse surgery. The recurrence rate of native-tissue repair has recently been adjusted, and estimation is now less than initially assumed and considered to be closer 10 % than 30 %. In this study, the overall reoperation rate was only 1.1 % in both groups. This can, of course, be explained by the relatively short observational time of 12 months. However, it is still a low reoperation rate compared with other studies. The recalculated recurrence rate may undermine the use of mesh altogether [2], especially if using mesh increases the risk of complications. Even though RCTs are considered the gold standard when comparing operative procedures, such studies are difficult to perform and often only include a small number

of patients, as illustrated above. Cohorts are thus often too small to detect differences in rare outcomes and complications.

This study shows that about one in five women have some kind of complication after the operation. This is a relatively high number. Patient-reported complications between 8 weeks and 1 year were more often seen in the native-tissue group. However, we have no information about the kind of complications and their severity. In contrast, doctor-reported complications within 12 months were comparable between groups. Only a few were organ lesions, which is the most feared complication, and few needed hospitalization. Postoperative doctor examinations were only performed if a woman had a complaint. This might conceal any asymptomatic complication. Not all mesh exposures are symptomatic, and therefore the actual exposure incidence might be higher than estimated when using patient-reported outcomes only [20]. In this study, we have no objective information on the rate of mesh exposure.

Dyspareunia is a common complication after posterior vaginal repair. A meta-analysis of several studies showed that 18 % of women experience dyspareunia after traditional posterior colporrhaphy or site-specific repair [1]. A known risk factor for dyspareunia seems to be levatorplasty. Moreover, vaginal mesh implant in an RCT was a risk factor of dyspareunia [21]. In our study, a high proportion of patients experienced de novo dyspareunia; however, the sexual questionnaire had a high proportion of missing values, making results less reliable. After sensitivity analysis for missing data, the rate of de novo dyspareunia was comparable with that presented in the literature. No difference was found between groups. This is in accordance with findings from a review from 2012 showing comparable risk of dyspareunia after both native-tissue and mesh repair [22]. We have no information regarding causes of dyspareunia, including the use of levatorplasty. Given the risk of dyspareunia after operation, it seems recommendable to inform patients preoperatively about this risk.

Another important functional outcome to evaluate after posterior wall repair is bowel function. In our study, most women had improved bowel emptying. However, worsened or de novo problems were found in nearly half of the patients. This in accordance with previous findings after site-specific repair [23], whereas defecatory dysfunction is only found in 17 % after native-tissue repair in the International Conference on Incontinence (ICI) review [1].

Observational studies imply the risk of confounding. In our study, patients in the mesh group had more pronounced prolapse and were older than women in the native-tissue repair group. Our results were adjusted accordingly in an attempt to minimize confounding. However, these differences might implicate a lower success rate, thus underestimating the positive effect of mesh repair. Moreover, the mesh group was much smaller than the native-tissue repair group, which might implicate that surgeons are not as familiar with the operation technique for mesh as they are for native-tissue repair. Despite these limitations, this study gives important information about effects and complications after both native-tissue and mesh repair of the posterior vaginal wall.

The perspectives of this study are that when operating primary isolated rectocele with native-tissue repair, women's assessment of cure rate, satisfaction, and improvement, are high and the rate of serious complications is low. This study does not suggest any advantage of using synthetic mesh when operating primary rectocele, but future studies are needed to evaluate long-term outcomes, including both benefits and complications following mesh repair, since this study was limited to a 1-year follow-up.

## Conclusion

In this study based on data from the Swedish National Register for Gynaecological Surgery, most patients were cured and satisfied after native-tissue repair of the posterior vaginal wall. Patient-reported outcomes 12 months after operation were comparable with results after mesh repair. The risk of serious complications and reoperation were comparable between groups. This suggests that native-tissue repair is suitable as the standard operation in patients with primary rectocele.

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**Author contribution** LD Madsen: data setup and analysis, statistical analysis, writing process.

## Compliance with ethical standards

**Consent** All women were informed that they could decline to participate in The Swedish National Register for Gynaecological Surgery. This study was approved by the Ethics Committee University of Umeå, Sweden (Dnr 08–076 M).

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