Trocar-Guided Mesh Compared With Conventional Vaginal Repair in Recurrent Prolapse

A Randomized Controlled Trial

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OBJECTIVE: To compare efficacy and safety of trocar-guided tension-free vaginal mesh insertion with conventional vaginal prolapse repair in patients with recurrent pelvic organ prolapse.

METHODS: Patients with recurrent pelvic organ prolapse stage II or higher were randomly assigned to either conventional vaginal prolapse surgery or polypropylene mesh insertion. Primary outcome was anatomic failure (pelvic organ prolapse stage II or higher) in the treated vaginal compartments. Secondary outcomes were subjective improvement, effects on bother, quality of life, and adverse events. Questionnaires such as the Incontinence Impact Questionnaire and Urogenital Distress Inventory were administered at baseline, 6 months, and 12 months. Anatomic outcomes were assessed by an unblinded surgeon. Power calculation with α=0.05 and β=0.80 indicated that 194 patients were needed.

RESULTS: Ninety-seven women underwent conventional repair and 93 mesh repair. The follow-up rate after 12 months was 186 of 190 patients (98%). Twelve months postsurgery, anatomic failure in the treated compartment was observed in 38 of 84 patients (45.2%) in the conventional group and in eight of 83 patients (9.6%) in the mesh group (P<.001; odds ratio, 7.7; 95% confidence interval, 3.3–18). Patients in either group reported less bulge and overactive bladder symptoms. Subjective improvement was reported by 64 of 80 patients (80%) in the conventional group compared with 63 of 78 patients (81%) in the mesh group. Mesh exposure was detected in 14 of 83 patients (16.9%).

CONCLUSION: At 12 months, the number of anatomic failures observed after tension-free vaginal mesh insertion was less than after conventional vaginal prolapse repair. Symptom decrease and improvement of quality of life were equal in both groups.

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Conventional surgical repairs of pelvic organ prolapse are associated with high failure rates. Anterior vaginal wall prolapse may recur in 30–70% of patients after standard anterior colporrhaphy,[1–3] whereas recurrence rates in the posterior compartment after posterior colporrhaphy are only 12–20%.[4,5] In the perspective of these high failure rates, particularly in the anterior compartment, vaginal surgery with prosthetic mesh has been introduced. The use of these synthetic meshes and biologic grafts in pelvic

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reconstructive surgery has increased considerably in recent years. Anatomic results of prolapse repair with synthetic mesh seem promising with success rates ranging from 71% to 100%.[6] The first randomized controlled trials comparing mesh with standard colporrhaphy showed failure rates of 6.7–11% after anterior mesh repair.[2,3,7] Two other recent trials showed substantially higher failure rates after mesh repair of either the anterior or the anterior and posterior compartment (19–28%).[8,9] All the previous trials mainly focused on anatomic outcome in the anterior compartment and had heterogeneous patient populations with primary as well as recurrent pelvic organ prolapse. Because the longest documented follow-up time of mesh-reinforced prolapse surgery is 38 months in only one study, and therefore no solid evidence on the long-term safety of synthetic mesh in pelvic reconstructive surgery exists, we limited our study to patients with recurrent pelvic organ prolapse.[10]

The aim of this study was to compare anatomic and subjective failure rates in all treated vaginal compartments of women with recurrent pelvic organ prolapse after tension-free vaginal mesh insertion (Prolift) and after conventional vaginal prolapse surgery. We hypothesized that the anatomic failure rate in the mesh group compared with the conventional repair group would be lower.

MATERIALS AND METHODS

This study was undertaken after obtaining approval from the Institutional Review Board of the St Elisabeth Hospital in Tilburg, The Netherlands, and the boards from all participating sites. All patients provided written informed consent before participation and were recruited in 13 centers in The Netherlands between June 2006 and July 2008. Women with a recurrent pelvic organ prolapse stage II or higher of the anterior wall, posterior vaginal wall, or both requiring surgical correction were eligible for participation. Exclusion criteria were pregnancy or contemplating future pregnancy, prior vaginal prolapse repair with mesh, a compromised immune system or any other condition that would compromise healing, previous pelvic irradiation or cancer, blood coagulation disorders, renal failure, upper urinary tract obstruction, renal failure and upper urinary tract obstruction, or presence of large ovarian cysts or myomas.

Baseline evaluation included medical history, a validated urogynecologic questionnaire, which among others, contains the Dutch validated Urogenital Distress Inventory, Defecatory Distress Inventory, Incontinence Impact Questionnaire, a gynecologic investigation, and pelvic organ prolapse quantification examinations.[11–13]

After obtaining the signature for the informed consent, patients were randomly assigned per center by a computer-generated schedule to either conventional vaginal prolapse surgery or tension-free vaginal mesh. Patients and surgeons were not blinded.

All procedures were performed by 22 participating gynecologists with broad experience in pelvic floor reconstruction and were specifically trained for the Prolift procedure by an authorized Prolift instructor before enrollment of patients. The number of prolapse repairs performed per surgeon in this study varied from one to 72.

The mesh insertions were performed as described in the article by Fatton et al[14] before enrollment of patients. To resemble daily gynecologic practice as close as possible, the type of conventional vaginal surgery was left at the discretion of the surgeon. Guidelines for conventional surgery were as follows. Anterior colporrhaphy was performed by a midline anterior vaginal incision, dissection of the vaginal epithelial layer from the fibromuscular layer, midline plication of the fibromuscular layer with delayed absorbable material, optional excision of excess vaginal mucosa, and incision closure with delayed absorbable material. Apical compartment prolapse (uterus, vaginal vault, or cervix) was treated according to the surgeon's preference. Vaginal hysterectomy, modified Manchester-Fothergill procedure,[15] uterosacral vaginal suspension (McCall procedure), and sacrospinous ligament fixation techniques were all allowed. Posterior colporrhaphy was performed through a posterior midline vaginal incision, dissection of the vaginal epithelial layer from the fibromuscular layer, midline plication of the fibromuscular layer with delayed absorbable material, optional excision of excess vaginal mucosa, and incision closure with delayed absorbable material. Reconstruction of the perineum (perineoplasty) was left to each surgeon's discretion. In the conventional group, the use of adjunct mesh was not allowed.

The tension-free vaginal mesh procedure was performed as described in the article by Fatton et al.[14] As recommended by these authors, a midline incision was made, which included full thickness of the fibromuscular wall of the vagina. The vagina was closed without any resection of vaginal tissue. No simultaneous hysterectomy or T incisions were allowed to reduce the chance of mesh exposure and erosions.[14] Other additional conventional surgery such as sacro-

spinous ligament fixation or modified Manchester-Fothergill was permitted.

Preoperatively a single dose of intravenous antibiotic prophylaxis (cefazolin-Natrium and metronidazole or amoxicillin and clavulanic acid) was given to all patients. An indwelling urinary catheter and vaginal gauze pack were left after completion of surgery according to local protocol.

Postoperative evaluations were performed during the hospital stay, at 6 weeks, and 6 and 12 months, respectively. Pelvic organ prolapse quantification measurements were recorded and Urogenital Distress Inventory, Defecatory Distress Inventory, Incontinence Impact Questionnaire, and Patient Global Impression of Improvement questionnaires completed at 6 and 12 months.[16]

The primary end point was anatomic failure in any of the treated vaginal compartments, defined as pelvic organ prolapse stage II or higher. The treated compartment in the tension-free vaginal mesh group was defined as anterior in case a patient underwent an anterior tension-free vaginal mesh procedure; anterior, posterior, and apical in case of a total tension-free vaginal mesh procedure; and posterior and apical in case of a posterior tension-free vaginal mesh procedure. Additional conventional surgery in any of the other vaginal compartments in the tension-free vaginal mesh group was allowed but not considered a treated compartment.

Treated compartment in the conventional group was defined as anterior in case a patient underwent anterior colporrhaphy; posterior if a patient underwent a posterior colporrhaphy; and apical if a patient underwent sacrospinal fixation, vaginal hysterectomy with uterosacral vaginal suspension, or a modified Manchester-Fothergill.

Secondary outcomes were duration of surgery, blood loss, length of hospitalization, complications and subjective improvement (Patient Global Impression of Improvement), and change in bother and quality of life measured by Urogenital Distress Inventory, Defecatory Distress Inventory, and Incontinence Impact Questionnaire scores. Pain was a secondary outcome as well and considered significant if a patient responded "yes, moderately to quite a bit" to the question "Do you experience pain in the lower abdomen or genital region?" Dyspareunia was considered significant if a patient responded "yes; moderately to quite a bit" to the question "Do you experience pain during intercourse?" Stress urinary incontinence was considered significant if a patient responded "yes, moderately to quite a bit" to the question "Do you experience urinary leakage during physical activity, coughing, or sneezing?"

Sample size calculation was based on the assumption of an estimated overall failure rate of 30% in the conventional surgery group (cure rate of 70%) and a 13% failure rate in the tension-free vaginal mesh group (cure rate of 87%).[1,4,14,17] Using a two-tailed hypothesis test with type I error of 5% and 80% power, 88 patients would be required in each group to detect a significant difference of at least 17% in pelvic organ prolapse stage II or higher. Anticipating a 10% dropout rate, we planned to enroll 194 patients.

Statistical analysis was performed using Statistical Package for the Social Sciences 15.0. Continuous variables were compared using the independent-samples *t* test to compare means or Mann-Whitney *U* test to compare medians. Categorical variables were compared using the chi square test. Related samples were compared using the paired-samples *t* test to compare means or the Wilcoxon signed rank test to compare medians. A *P* value of $<.05$ was considered statistically significant.

RESULTS

One hundred ninety-four patients were enrolled and assigned to either conventional vaginal prolapse repair or to trocar-guided tension-free vaginal mesh insertion (Fig. 1). Two patients in each arm did not undergo surgery. The follow-up rate after 12 months was 186 of 190 patients (98%). Three patients in the tension-free vaginal mesh arm and one in the conventional arm did not return for follow-up nor completed the urogynecologic questionnaires that were sent to them.

Baseline characteristics did not differ between the two groups apart from a higher number of previous sacrocolpopexies in the tension-free vaginal mesh group (Table 1). Peri- and postoperative characteristics are shown in Table 2. The duration of surgery was a median 8.5 minutes longer in the tension-free vaginal mesh group. In none of the patients did blood loss exceed 500 mL. Hematomas were seen more frequently in the tension-free vaginal mesh group (Table 3). One patient in the conventional group needed surgical reintervention for postoperative hemorrhage. No major complications occurred during surgery or in the immediate postoperative period. Temporary urinary retention was the most common complication in both groups but occurred significantly more often in the tension-free vaginal mesh group. Normal micturition restored spontaneously in all patients within 14 days.

In 14 of 83 patients (16.9%) in the tension-free vaginal mesh group, mesh exposure was detected, in seven patients at the 6-month follow-up visit and in

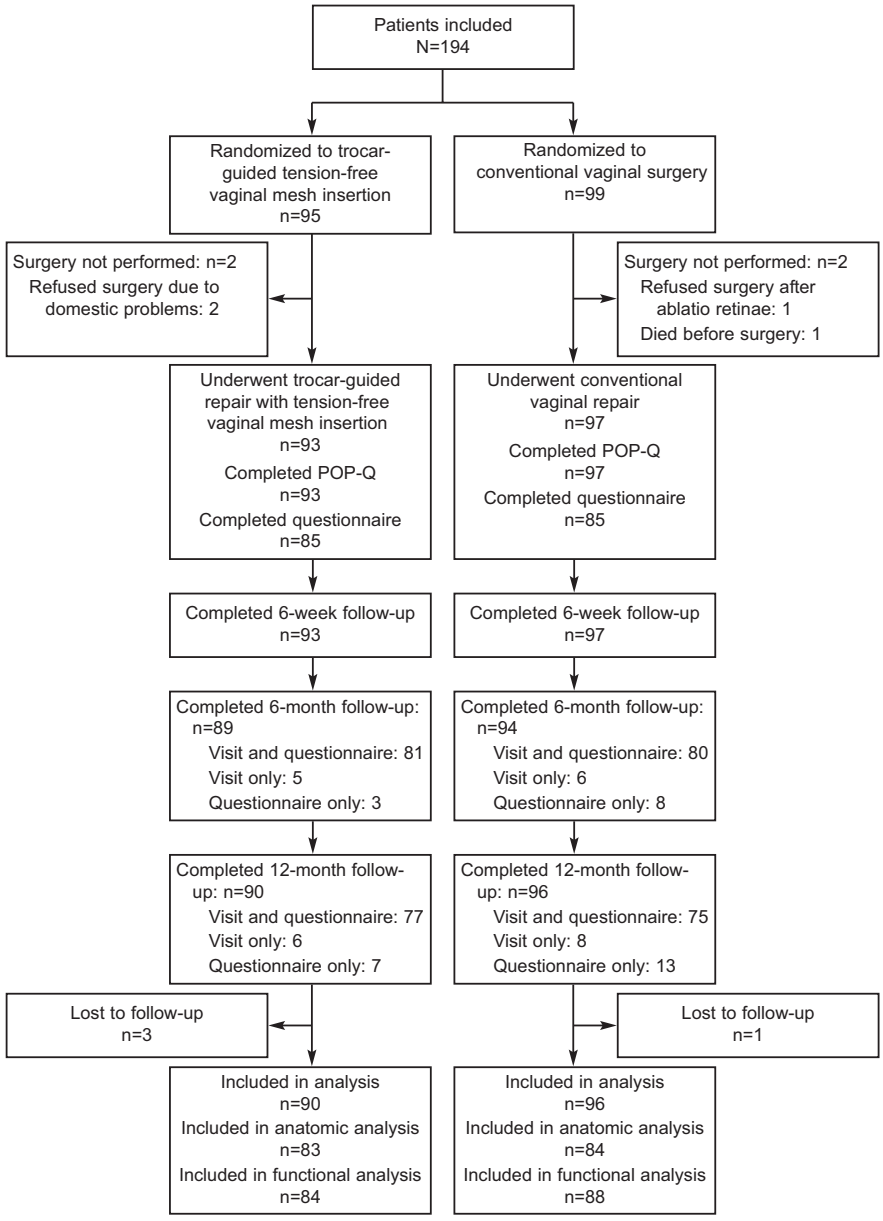

Fig. 1. Patient enrollment and follow-up. POP-Q, pelvic organ prolapse quantification.

Withagen. Recurrent POP: Mesh or Conventional Repair. Obstet Gynecol 2011.

seven cases at the 12-month follow-up visit. Nine of these 14 patients were asymptomatic. The size of these mesh exposures varied from 2 to 20 mm. Mesh exposures were equally distributed over the anterior and posterior compartments. The mesh exposure rates per center varied from 0% to 100% (median 0%). In five patients, these mesh exposures were excised and the defects covered with vaginal mucosa in a day-care procedure after patients were initially treated with local estrogen. These exposures resolved. The other nine patients were treated with local estrogen only; two exposures resolved and the other seven were still under observation at the 12 months follow-up visit.

At 12 months, pain in the lower abdomen or in the genital area was reported by 10 of 85 patients (11.7%) in the conventional group and by eight of 79 patients (10%) in the tension-free vaginal mesh group (Table 3). Because we missed data on pain in 23 patients in the conventional group and on 22 patients in the tension-free vaginal mesh group, we performed a missing data analysis. The nonresponders were a mean 4.9 years older compared with the responders. All other factors (body mass index, comorbidity, preoperative pelvic organ prolapse stage, treatment group, complication, failure) were equal.

Preoperatively, 49 of 97 (51%) patients in the conventional and 52 of 93 (56%) in the mesh repair

Table 1. Patient Characteristics

	Conventional (n=97)	Vaginal Mesh (n=93)	*P*
Age	64±10.2	64±10.5	.96
Parity	2 (1–5)	2 (0–6)	.74
Body mass index	27±4	27±6	.54
Comorbidity	46 (47)	40 (43)	.54
Previous surgery			
Abdominal hysterectomy	14 (14)	20 (22)	.20
Vaginal hysterectomy	69 (71)	56 (60)	.11
Anterior colporrhaphy	69 (71)	54 (58)	.06
Posterior colporrhaphy	61 (63)	51 (55)	.26
Sacrospinous ligament fixation	0	3 (3)	.08
Sacrocolpopexy	6 (6)	17 (18)	.01
One prolapse procedure	81 (84)	81 (87)	.49
More than one	16 (16)	12 (13)	.49
Previous incontinence surgery	23 (24)	19 (20)	.59
Overall POP stage			.66
II	47 (49)	42 (45)	
III	45 (46)	46 (50)	
IV	5 (5)	5 (5)	
Treatment anterior compartment	56	58	.51
POP stage I, II, III, IV	5, 28, 20, 3	0, 25, 31, 2	.053
Treatment posterior compartment	64	56	.41
POP stage I, II, III, IV	6, 29, 28, 1	5, 33, 17, 1	.33
Treatment apical compartment	45	56	.056
POP stage 0, I, II, III, IV	25, 4, 10, 3, 3	35, 11, 2, 4, 4	.349

POP, pelvic organ prolapse.
Data are mean (±standard deviation), median (range), or n (%) unless otherwise specified.

Table 2. Perioperative and Postoperative Data

	Conventional (n=97)	Vaginal Mesh (n=93)	*P*
Anterior vaginal mesh	0	37 (40)	
Posterior vaginal mesh	0	35 (38)	
Anterior+posterior vaginal mesh	0	1 (1)	
Total vaginal mesh	0	20 (21)	
(Concomitant) surgery		21 (23)	
Vaginal hysterectomy	4 (4)	0	
Anterior colporrhaphy	56 (58)	3 (3)	
Posterior colporrhaphy	64 (66)	3 (3)	
Perineoplasty	8 (8)	1 (1)	
Manchester-Fothergill	2 (2)	2 (2)	
Enterocele repair	10 (10)	0	
Monarc/TVT/TVT-O	1 (1)	4 (4)	
Sacrospinous ligament fixation	39 (40)	5 (5)	
Uterosacral vaginal suspension	4 (4)	0	
Spinal analgesia	63 (66)	57 (61)	.47
General analgesia	32 (34)	36 (39)	.47
Operating time (min)	45 (16–120)	53.5 (29–125)	.001
Blood loss (mL)	100 (0–400)	100 (0–400)	.15
Duration urinary catheter (d)	2 (1–6)	2 (1–10)	.27
Hospital stay (d)	3 (2–13)	3 (2–15)	.97

TVT, tension-free vaginal tape; TVT-O, tension-free vaginal tape obturator.
Data are n (%) or median (range) unless otherwise specified.

group were sexually active (Table 3). At 12 months, 51 of 97 (53%) of the conventional and 53 of 93 (57%) of the tension-free vaginal mesh repair patients were sexually active. In both groups, rates of dyspareunia had decreased at 12 months compared with baseline. The difference in reported dyspareunia between groups was not significant either at baseline or at 12 months. At 12 months, de novo dyspareunia was reported by three of 29 (10%) in the conventional and three of 37 (8%) in the tension-free vaginal mesh repair group (Table 3).

At 12 months, de novo stress urinary incontinence was found in eight of 88 (9%) in the conventional group and in eight of 81 (10%) in the tension-free vaginal mesh group. If we look only at the treated anterior compartment, the rates of de novo stress urinary incontinence are 11% (six of 53) and 12% (six of 50) for the conventional group and the tension-free vaginal mesh group, respectively.

Six and 12 months postsurgery, the pelvic organ prolapse quantification points Aa, Ba, C, GH, PB, Ap, Bp, and D improved significantly ($P<.05$) in both groups (Table 4.), but results were better in the tension-free vaginal mesh group compared with the conventional group with respect to points Aa, Ba, PB, Ap, and Bp. Anatomic failures in the treated compartments were observed in 38 of 84 patients (45.2%) in the conventional group and eight of 83 patients (9.6%) in the tension-free vaginal mesh group (Table 5). The difference in failure rates remained highly significant even if the lost-to-follow-up patients in the tension-free vaginal mesh group were all considered failures and in the conventional group were all considered successes (38 of 97 [39%] compared with 18 of 93 [19%], $P<.003$) (odds ratio, 2.7; 95% confidence interval, 1.4–5.2). In the conventional group, four patients underwent reoperation within 12 months as a result of symptomatic recurrence in the treated compartment. Two anterior tension-free vaginal mesh

Table 3. Complications

Complication	Conventional (n=97)	Vaginal Mesh (n=93)	*P*
Bladder perforation	0	2 (2)	.15
Repeat surgery for postoperative hemorrhage	1 (1)	0	.33
Hematoma	1 (1)	6 (6)	.047
Temporary urinary retention	5 (5)	15 (16)	.008
Buttock pain	1 (1)	0	.33
Cumulative mesh exposure at 12 months	—	14 (16.9)	<.001
Pain (lower abdomen or genital area)			
Baseline	24/79 (30)	18/81 (22)	.24
At 12 months	10/85 (11.7)	8/79 (10)	.74
De novo pain	2/50 (4)	4/53 (7.5)	.44
Dyspareunia			
Baseline	16/49 (33)	13/52 (25)	.39
At 12 months	12/51 (24)	9/53 (17)	.41
De novo dyspareunia	3/29 (10)	3/37 (8)	.75
Stress urinary incontinence			
Baseline	11/84 (13)	15/84 (18)	.39
At 12 months	8/87 (9)	14/81 (17)	.12
De novo SUI	8/88 (9)	8/81 (10)	.86

Data are n (%) unless otherwise specified.

repairs, one posterior tension-free vaginal mesh repair and one Labhardt procedure, were performed. In the tension-free vaginal mesh group, no reinterventions resulting from symptomatic recurrence were reported. In the conventional group, failure rates were higher in both the anterior as well as in the posterior compartment compared with the tension-free vaginal mesh group (Table 5). No differences in the failure rate of the apical compartment were detected. Analysis of the apical compartment was conducted after exclusion of seven patients in the tension-free vaginal mesh group who underwent additional conventional apical repair (two underwent a Manchester-Fothergill and five underwent sacrospinous ligament fixation). The failure rate per center in the conventional group varied from 0% to 100% (median 45%) and in the tension-free vaginal mesh group, the failure rate per center varied also from 0% to 100% (median 0%). If we would have defined failure as an overall pelvic organ prolapse stage II or more (ie, leading edge of any compartment and thus not limited to treated compartment) or repeat prolapse surgery, the "failure rate" in the conventional group would have been 66% (56 of 84 patients) and 49% (41 of 83 patients) in the tension-free vaginal mesh group (P=.03).

The Urogenital Distress Inventory, Defecatory Distress Inventory, and Incontinence Impact Questionnaire domain scores were similar at baseline in the two treatment arms, except for the domain "mobility" of the Incontinence Impact Questionnaire (Table 6). At 12 months, significant improvements in the Urogenital Distress Inventory domains "genital prolapse," "pain" and "overactive bladder," and "physical functioning" of the Incontinence Impact Questionnaire were noted in both groups. Defecatory Distress Inventory domains "pain" and "incontinence" scored significantly better in the tension-free vaginal mesh group compared with the conventional group at 12 months.

The Patient Global Impression of Improvement scores at 12 months showed no difference in patients' perception of improvement between groups; 64 of 80 patients (80%) in the conventional group reported

Table 4. Pelvic Organ Prolapse Quantification Measurements at Baseline, 6 Months, and 12 Months Postsurgery

	Baseline		*P*	6 Months		*P*	12 Months		*P*
POP-Q Point	Conventional (n=94)	Vaginal Mesh (n=93)	Conventional Compared With Vaginal Mesh	Conventional (n=80)	Vaginal Mesh (n=84)	Conventional Compared With Vaginal Mesh	Conventional (n=82)	Vaginal Mesh (n=83)	Conventional Compared With Vaginal Mesh
Aa	−1 (−3 to 3)	0 (−3 to 3)	.385	−2 (−3 to 3)*	−3 (−3 to 1)*	.001	−2 (−3 to 3)†	−3 (−3 to 2)†	<.001
Ba	0 (−3 to 6)	1 (−3 to 6)	.142	−2 (−3 to 4)*	−3 (−3 to 2)*	.001	−2 (−3 to 5)†	−3 (−3 to 3)†	<.001
C	−5 (−9 to 8)	−5 (−10 to 7)	.421	−7 (−10 to 4)*	−8 (−10 to 0)*	.621	−7 (−9 to 5)†	−8 (−9 to 5)†	.077
GH	4 (2 to 8)	4 (2 to 8)	.038	3 (1 to 6)*	3 (1 to 7)*	.705	3 (1 to 6)†	3 (1 to 6)†	.561
PB	4 (1 to 7)	3 (1 to 7)	.062	4 (1 to 6)*	3 (2 to 5)*	.018	3 (1 to 6)†	3 (2 to 6)†	.018
TVL	9 (4 to 12)	9 (5 to 12)	.338	9 (4 to 11)*	9 (5 to 10)*	.539	9 (4 to 10)†	9 (5 to 11)†	.216
Ap	0 (−3 to 3)	−1 (−3 to 3)	.031	−2 (−3 to 2)*	−3 (−3 to 2)*	.136	−2 (−3 to 3)†	−3 (−3 to 1)†	.017
Bp	0 (−3 to 6)	−1 (−3 to 6)	.024	−2 (−3 to 2)*	−3 (−3 to 3)*	.220	−2 (−3 to 5)†	−3 (−3 to 2)†	.026
D	−6 (−9 to −1)	−6 (−9 to −1)	.621	−7 (−9 to −2)*	−8 (−10 to −3)*	.090	−8 (−9 to −6)†	−8 (−10 to −5)†	.860

POP-Q, pelvic organ prolapse quantification.
Data are median (range) unless otherwise specified.
* P<.05 within group baseline compared with 6 months.
† P<.05 within group baseline compared with 12 months.

Table 5. Failure (Stage II or Greater or Repeat Surgery in Treated Compartment)

	6 Months			12 Months				
	Conventional	Vaginal Mesh	*P*	Conventional	Vaginal Mesh	*P*	OR (95% CI)	RR
All patients	33/86 (38.4)	5/86 (5.8)	<.001	38/84 (45.2)	8/83 (9.6)	<.001	7.7 (3.3–18)	4.7
Compartment								
Anterior	20/45 (44.4)	4/54 (7.4)	<.001	27/49 (55.1)	4/51 (7.8)	<.001	14.4 (4.5–46)	7.0
Posterior	11/57 (19.3)	2/48 (4.2)	.019	14/57 (24.5)	2/49 (4.1)	.003	7.7 (1.6–36)	6.0
Apical	2/34 (5.9)	1/44 (2.3)	.96	1/40 (2.5)	3/48 (6.3)	.40	—*	—*

OR, odds ratio; CI, confidence interval; RR, relative risk.
Data are n/N (%) unless otherwise specified.
* Too few cases to allow estimation of the OR or RR.

improvement compared with 63 of 78 patients (81%) in the tension-free vaginal mesh group.

DISCUSSION

This randomized controlled trial of mesh insertion compared with conventional vaginal repair in women with recurrent pelvic organ prolapse demonstrated significant lower failure rates in the anterior as well as the posterior compartment after tension-free vaginal mesh insertion. At the end point, 12 months, most of the anatomic failures, however, were pelvic organ prolapse stage II and not bothersome enough to lead

Table 6. Effect of Surgery on Symptoms and Health-Related Quality-of-Life Scores

	Baseline		6 Months		12 Months		*P* Within Group (Conventional, Vaginal Mesh)	*P* Between Groups (Conventional Compared With Vaginal Mesh; Baseline, 6 Months, 12 Months)
	Conventional (n=85)	Vaginal Mesh (n=85)	Conventional (n=88)	Vaginal Mesh (n=84)	Conventional (n=88)	Vaginal Mesh (n=84)		
UDI								
Genital prolapse	50 (±34)	48 (±34)	6 (±17)	7 (±19)	5 (±17)	6 (±17)	<.001, <.001	.969, .652, .661
OAB	34 (±27)	59 (±27)	19 (±23)	20 (±23)	21 (±21)	19 (±24)	<.001, <.001	.716, .812, .420
Incontinence	23 (±22)	24 (±26)	20 (±22)	20 (±22)	19 (±19)	22 (±25)	.132, .689	.140, .680, .060
Obstructive micturition	26 (±27)	27 (±31)	15 (±21)	19 (±27)	16 (±23)	18 (±26)	.003, .121	.070, .191, .286
Pain	29 (±27)	25 (±26)	15 (±20)	14 (±22)	15 (±21)	13 (±22)	<.001, .001	.581, .346, .945
DDI								
Constipation	11 (±17)	10 (±17)	8 (±16)	7 (±13)	9 (±17)	10 (±16)	.592, .999	.447, .170, .971
Obstructed defecation	14 (±16)	11 (±17)	7 (±12)	8 (±17)	10 (±15)	9 (±18)	.034, .259	.717, .417, .966
Pain	9 (±18)	8 (±18)	5 (±16)	4 (±13)	11 (±23)	4 (±10)	.244, .004	.739, .136, .013
Incontinence	10 (±18)	8 (±16)	10 (±20)	5 (±15)	13 (±23)	7 (±17)	.098, .559	.224, .028, .048
IIQ								
Physical functioning	28 (±28)	21 (±26)	13 (±22)	13 (±21)	13 (±20)	12 (±23)	<.001, .014	.471, .711, .605
Mobility	32 (±25)	23 (±24)	19 (±23)	16 (±20)	24 (±48)	17 (±22)	.440, .018	.028, .195, .349
Social functioning	19 (±22)	13 (±17)	9 (±13)	10 (±17)	11 (±16)	10 (±17)	.001, .096	.115, .447, .979
Embarrassment	14 (±20)	12 (±17)	10 (±17)	10 (±20)	9 (±19)	11 (±19)	.080, .461	.325, .723, .624
Emotional health	21 (±23)	18 (±24)	12 (±19)	13 (±21)	12 (±18)	16 (±22)	.001, .626	.729, .579, .090
PGI-I								
Very much better			18 (23)	20 (27)	19 (24)	18 (23)		—, .574, .920
Much better			35 (45)	33 (45)	35 (44)	36 (46)		—, .973, .761
A little better			14 (18)	7 (10)	10 (12)	9 (12)		—, .129, .852
No change			7 (9)	8 (11)	8 (10)	5 (6)		—, .704, .412
A little worse			1 (1)	4 (5)	1 (1)	5 (6)		—, .154, .089
Much worse			2 (3)	1 (1)	2 (3)	3 (4)		—, .591, .628
Very much worse			1 (1)	1 (1)	1 (1)	2 (3)		—, .970, .545
Reoperation (prolapse)					4 (5)	0		—

UDI, Urogenital Distress Inventory; OAB, overactive bladder; DDI, Defecatory Distress Inventory; IIQ, Incontinence Impact Questionnaire; PGI-I, Patient Global Impression of Improvement.
Data are mean (±standard deviation) or n (%) unless otherwise specified.
Scores range between 0 (least bother) to 100 (maximum bother).
— Too few cases to perform χ^2 test.

to the necessity of reintervention. The anatomic failure rates of anterior colporrhaphy and posterior colporrhaphy in this study were slightly higher when compared with other studies that describe heterogeneous populations of primary and recurrent pelvic organ prolapse.[2–5,7] Our population, however, only consisted of women with recurrent pelvic organ prolapse and this might explain this slightly higher failure rate in the conventional group compared with data from the literature. Anatomic failure rates in the tension-free vaginal mesh group are consistent with or even lower than rates reported in previous studies.[2,3,7–9,18]

Although anatomic support at 12 months was superior in the tension-free vaginal mesh group, bulge and overactive bladder symptoms improved significantly in both treatment groups and the overall subjective improvement was equal among both groups. Our stringent definition of anatomic failure does explain the high number of asymptomatic patients with failed anatomic results at 12 months postsurgery. However, these asymptomatic patients with pelvic organ prolapse stage II could be forerunners and might develop complaints within a few years. Longer follow-up is therefore mandatory and will be conducted and documented in a following study.

The effects of long-term presence of nonabsorbable mesh in the vagina is unknown and a reason for concern. Vaginal mesh exposure was detected in 16.9% of tension-free vaginal mesh patients, which is higher than most authors previously reported.[2,3,8,9,18,19] In two other studies, however, exposure rates of 17.3–20% were reported.[7,20] Known risk factors for exposure are concurrent vaginal hysterectomy, T incisions, age older than 70 years, and smoking.[20–22] In our study, the tension-free vaginal mesh procedure was not combined with hysterectomy nor with T incisions. Two of 14 patients with mesh exposure were older than 70 years of age. Smoking was not a recorded variable. All participating centers were strictly instructed to search for any mesh exposure at each of the follow-up visits. This could have contributed to this higher rate of exposure. Another explanation for this fairly high rate of exposure could be the fact that in this multicenter trial of 13 participating centers, 22 surgeons, although all with an adequate level of experience, had their own learning curve. Exposure rates per center varied from 0% to 100%. Furthermore, the patient population only consisted of patients with recurrent pelvic organ prolapse, so more scar tissue of previous surgeries was present, which could have led to faulty or delayed healing with subsequent exposure. Given the 45.2% failure rate after conventional vaginal prolapse surgery and 9.6% failure rate after tension-free vaginal mesh repair, the number needed to treat for benefit would be 2.8. Given the 16.9% vaginal mesh exposure rate, the number needed to harm would be six.

De novo pain and de novo dyspareunia rates were low and equally distributed among both groups. Because de novo dyspareunia rates of 13–42% have been reported in the literature after conventional vaginal prolapse surgery and after mesh repair, our rates in either group compare favorably.[8,23,24]Unlike the higher rate of de novo stress urinary incontinence after mesh surgery in a previous study, we found an equal rate of de novo stress incontinence (9% and 10%) in both groups.[7] A possible explanation could be the high rate of previous surgery for urinary incontinence of 20% and 24% and the 100% rate of previous prolapse surgery.

The strength of this study was that it is a randomized controlled trial that used validated outcome measures. Another strength is the design of the study, in which a new surgical technique, ie, pelvic organ prolapse reconstruction with mesh, is compared with conventional day-to-day vaginal techniques of pelvic organ prolapse repair. Furthermore, because 13 centers with a total of 22 gynecologic surgeons participated in this study, we consider the outcomes applicable to a broader population.

However, this study was subject to several limitations as well. The relatively short follow-up period of 12 months may have limited the detection of potential small differences in quality-of-life outcome scores. Although the total lost to follow-up rate of 2% (four of 194) was low, of 42 of 194 patients (22%), some part of the follow-up data was missing. This could certainly bias our findings; however, the anatomic results remain highly significant if all the lost-to-follow-up patients in the tension-free vaginal mesh group would be considered failures and the lost-to-follow-up patients in the conventional group would be considered successful. The postoperative pelvic organ prolapse quantification measurements were performed by the surgeon or an available experienced colleague of the surgeon working in the same hospital but, unfortunately, not by an independent clinical examiner. This could have led to lower recurrence rates, because surgeons might overrate the results of their own procedures. However, because they judged both mesh and conventional repairs, it seems probable that this bias would then be equally distributed over both techniques.

Despite these limitations, this study is one of few randomized controlled trials comparing conventional vaginal prolapse repair with polypropylene-reinforced

mesh repair only in women with recurrent pelvic organ prolapse. Our results demonstrate equal improvements in symptoms as well as in physical functioning at 12 months, but the tension-free vaginal mesh group was associated with a significantly lower anatomic failure rate.

Moreover, this study not only demonstrates lower anatomic failure rates in the anterior compartment, but in the posterior compartment as well.[25] Because the long-term effects and safety of mesh-reinforced repairs are not yet fully known, surgeons may consider these procedures primarily for recurrent vaginal prolapse after counseling patients on the risks and benefits. New innovations aiming at strong tissue support with lower exposure rates should be the subject for future research and need to be evaluated in the context of further prospective randomized trials.

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