

## CLINICAL STUDY

# Single-incision mesh vs sacrospinous ligament fixation in posthysterectomy women at a three-year follow-up: a randomized trial

Galad J<sup>1,2</sup>, Papcun P<sup>3</sup>, Dudic R<sup>2</sup>, Urdzik P<sup>1,2</sup>

Gynaecological Department, Gynpor, s.r.o, Sliac, Slovakia. peter.urdzik@upjs.sk

**ABSTRACT**

**OBJECTIVES:** The primary clinical objective was to prospectively compare the effectiveness of the "single-incision MESH" technique versus sacrospinous ligament fixation (ACSSF) in correcting the defect of pelvic organ prolapse (POP) in the anterior and apical compartments. Their effectiveness was assessed at a 1-year/3-year follow-up (FU).

**METHODS:** In the period of 2013–2015, we have randomized 146 women into two groups, namely 73 into ACSSF group and 73 into MESH group

**RESULTS:** At 1-year/3-year FU, we achieved an effectiveness of 92 %/87 % in the point Ba ( $\leq -1$  cm) in the MESH group (48/52; 40/46) vs 70 %/66 % in the ACSSF group (35/50; 30/45); ( $p = 0.005/p = 0.021$ ).

At 1-year/3-year FU, in the area of point C ( $\leq -1$  cm), we achieved a 94 %/91 % effectiveness in the MESH group (49/52; 42/46) vs 90 %/80 % in the ACSSF group (45/50; 36/45); ( $p = 0.005/p = 0.192$ ). In the MESH group, we observed a more frequent occurrence of "de novo" SUI (11 % vs 6 %) and a defect in the unoperated (posterior) compartment (18 % vs 8 %); the difference was not statistically significant.

**CONCLUSION:** Our study showed that the vaginal synthetic mesh repair of POP did not improve women's outcomes in terms of effectiveness or adverse effects, while the patient satisfaction is the same as compared to that with sacrospinous ligament fixation at a 3-year FU. In gynecology, there are situations in which the comparison replaces the scientific solution (Tab. 5, Fig. 2, Ref. 50). Text in PDF [www.elis.sk](http://www.elis.sk)

**KEY WORDS:** sacrospinous ligament fixation, quality of life index, synthetic mesh, randomized trial, prolapse.

**Abbreviations:** 1 y-FU – 1-year follow-up, 3 y-FU – 3-year follow-up, ACSSF – Anterior colporrhaphy with sacrospinous fixation, AHYE – Abdominal hysterectomy, BMI – Body mass index, FDA – Food and drug administration, FU – Follow-up, IQoL – Quality of life index, LAVH – Laparoscopic assisted vaginal hysterectomy, LCFA – Last carried forward analysis, OAB – Overactive bladder, OABI – Overactive bladder improvement, POP – Pelvic organ prolapsed, POP-Q – Pelvic organ prolapse quantification, RUTC – Relapse in untreated compartment, SI – Stress incontinence, TNO – Total number of operations, TVL – Total vaginal length, VAS – Visual analogue scale, VHYE – Vaginal hysterectomy

**Introduction**

We got access to material in form of polypropylene meshes (MESH), which demonstrated good biocompatibility and promised the possibility of reliable replacement of defective tissues (1). Unfortunately, it was shown that their implantation also comes

with certain long-term risks that we have not encountered in classical techniques (2–4). At present, not only we are in a period of searching for a prudent indication for their use (5), but also, in some countries, there has been a complete ban on the production and distribution of vaginal meshes used in POP surgical treatment and stressed incontinence (6, 7).

The aim of the randomized study was to compare the effectiveness of the correction of a defect in the anterior and apical compartments by means of the "single incision MESH" technique versus classical surgical technique, as well as patient satisfaction with procedures by using scoring systems in the scope of surgical treatment of pelvic organs in patients after hysterectomy.

**Materials and methods**

This was a prospective randomized study. We formed two parallel groups of women who were to undergo a transvaginal concomitant anterior/apical compartment repair using the single-incision synthetic MESH technique or classical anterior repair with sacrospinous ligament fixation technique (ACSSF). The randomisation was performed by using an envelope before the surgery.

**Inclusion criteria**

a) age over 18 years, b) pelvic organ prolapse quantified as 3rd degree in anterior compartment and 2nd/3rd degree in apical

<sup>1</sup>Gynaecological Department, Gynpor, s.r.o, Sliac, Slovakia, <sup>2</sup>Department of Gynaecology and Obstetrics, Safarik University in Kosice, Slovakia, and <sup>3</sup>2nd Department of Gynecology and Obstetrics, Comenius University in Bratislava, Slovakia

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compartment, c) history of performed hysterectomy, d) signed informed content.

#### Exclusion criteria

a) concomitant operation (posterior prolapse pelvic repair), b) uterus *in situ*, c) POP-Q > 3.

#### Statistical analysis – chart flow power analysis

We planned to follow up 146 women in total (73 in each arm) to detect a difference in the primary clinical outcome POP-Q (Ba  $\leq -1$  cm; C  $\leq -1$  cm – POP-Q) of 20 % in favour of MESH group with 90 % power and  $\alpha = 0.05$ , where an efficacy of 70 % was assumed with standard vaginal surgery method without the synthetic mesh. The sample size was increased to 174 women to allow for a potential 15 % drop out.

In the period of 2013–2015, we identified 453 women with POP, of whom 223 were ineligible for the study, thus leaving us with 230 women eligible for randomisation, of whom however, 83 declined their participation. Finally, 146 women were randomised in the study. According to the selected operation technique, we prospectively, in form of a sealed envelope opened directly in the operation theatre, divided the 146 women into two

groups based on whether the correction was to be performed with MESH “single incision” technique (73 women) or classic technique, i.e anterior colporrhaphy with sacrospinous ligament fixation (ACSSF; 73 women). Due to complications during anaesthesia (diastolic blood pressure over 110 mmHg, allergic reaction to pharmacy, bronchospasm, etc.) the operation was not performed in 5 women (3 MESH/2 ACSSF) and other concomitant surgery had to be added in 14 women (6 MESH/8 ACSSF). Finally, the MESH surgery was performed in 64 women and ACSSF surgery in 63 women.

Figure 1 presents a detailed flowchart of patients randomized in the study.

#### Preoperative measurements

Medical history of each of the patients was obtained before the surgery, and each patient was physically examined in detail. For each patient in both groups, we determined the value of reference points Aa, Ba, C, Ap, Bp, Gh, Gp and tvl with the degree of the defect determined according to the POP-Q classification (8). The preoperative urine culture from each patient was negative. A coughing test with repositioning of the prolapse was conducted in every patient for determining the occult stress incontinence.

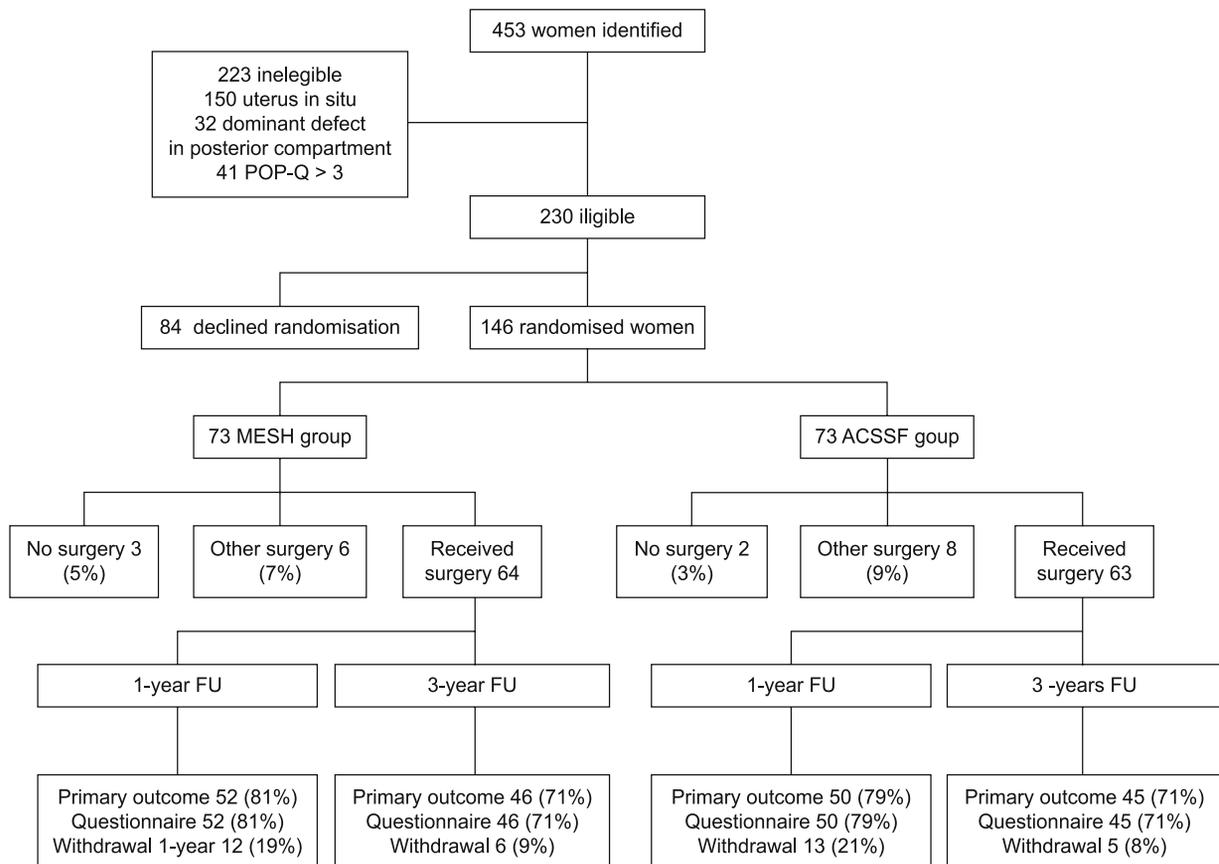


Fig. 1. Flowchart.

### Postoperative measurements.

We determined the degree of the defect according to the POP-Q upon admittance of each patient in both groups and then at 1-year and 3-year follow-ups. The correction was considered successful when the degree in the operated compartment was  $\leq 1$  (point Ba  $\leq -1$  cm; point C  $\leq -1$  cm) while a degree of  $\geq 2$  in the operated compartment according to POP-Q was considered to be a recurrence of the defect. We compared the results achieved in MESH and ACSSF groups using the chi-square test, and determined the statistical significance while  $p < 0.05$  was considered to be statistically significant.

### Surgical procedures

Every patient received antibiotic prophylaxis with Cefazolin 1 g 30 minutes before surgery; The Foley catheter was left for 24 hours and Betadine flush was performed for a period of 4–6 weeks.

In the MESH group, in the scope of reconstruction of the combined defect in the anterior and medial compartments, we introduced the implants Elevate Anterior & Apical or NUVIA SI anterior. The principle of this operation lies in the placement of the implant into the vesicovaginal space, and in direct fixation of the arms of the mesh to the sacrospinous ligament and obturator membrane using plastic anchors.

In the ACSSF group, in the scope of reconstruction of the combined defect in the anterior and medial compartments, we operated on patients with the technique of anterior colporrhaphy with sacrospinous ligament fixation. The principle of this operation is in the gathering of the vesicovaginal fascia and unilateral fixation of the vaginal stub to *ligamentum sacrospinousum* from the anterior colpotomy.

### Outcomes

The primary clinical outcome in form of surgical efficacy of the compared methods was defined as a maximum leading edge of  $< -1$  cm (POP-Q) at 1-year and 3-year follow-ups. The secondary outcome in form of patient satisfaction and improvement with procedures was determined by using scoring systems in form of visual analogue scale (VAS) and index of quality of life. We also observed adverse effects and complications of surgery (exposure of synthetic MESH, dyspareunia, *de novo* overactive bladder, and stress urinary incontinence, etc). We also reported the recurrence of prolapse in untreated (posterior) compartment.

### Statistical analysis

Quantitative data were expressed as average  $\pm$  standard deviation while qualitative data were expressed as percentage of the number of positive cases (n). The paired t-test was used for comparing quantitative parameters between individual groups. We examined the data for normal distribution and used Mann-Whitney test when normality was not met. The Chi-square test was used for comparing qualitative data between the groups. The paired t-test was used to compare the data in one group in different time horizons. The programs Microsoft Excel 365 ProPlus version 1811 and IBM SPSS Statistics version 20 were used for statistical

evaluations. All statistical evaluations were performed at the level of statistical significance  $p < 0.05$  (9).

### Ethics

The study protocol was approved by decision No. 1/2012 of the Ethics Committee of the Gynpor General Hospital, Sliac, Slovak Republic. At the same time, the protocols and informed consent were in line with legislation of the Slovak Republic pursuant to Act No. 122/2013 Coll. and Act No. 84/2014 Coll. The study protocol was carefully explained to each patient, and each patient signed the informed consent on inclusion in the study.

### Results

In the period of 2013–2015, we identified 453 women with POP, of whom 223 were ineligible for the study, thus leaving us with 230 women eligible for randomisation, of whom however, 83 declined their participation. Finally, 146 women were randomised in study. The surgery was performed in 64 women in the MESH group, and 63 women in the ACSSF group. Detailed analysis (surgery efficacy/questionnaire) was performed on the data from 102 women. We also performed an analysis with the inclusion of patients who failed to appear for the check-up or deliver the questionnaire. In Table 1, the patient baseline characteristics of the set are presented.

Table 2 presents an objective evaluation of points according to POP-Q classification before the operation and at 1-year and 3-year follow-ups.

### Primary outcome

#### Correction of defect in MESH group

We assigned 52 women with a combined defect in the anterior (POP-Q – 3) and medial compartments (POP-Q 2–3) to the MESH group. The characteristics of the set are presented in Table 1. Hysterectomy was performed in 52 of the women (100 %) in the

**Tab. 1 Patient baseline characteristics.**

Parameter	MESH (n=52)	ACSSF (n=50)	t-test <sup>a</sup> / chi-square test <sup>b</sup>
Age	63.1 $\pm$ 8.7	63.6 $\pm$ 8.7	0.745 <sup>a</sup>
Parity	2.6 $\pm$ 1.1	2.6 $\pm$ 1.5	0.947 <sup>a</sup>
BMI	27.4 $\pm$ 3.9	27.6 $\pm$ 3.8	0.729 <sup>a</sup>
LAVH	35% (18)	36% (18)	0.524 <sup>b</sup>
VAHYE	44% (23)	34% (17)	0.196 <sup>b</sup>
AHYE	21% (11)	30% (15)	0.213 <sup>b</sup>
Sexual activity	48% (25)	50% (25)	0.502 <sup>b</sup>
OAB	63% (33)	56% (28)	0.286 <sup>b</sup>
SI in history	21% (11)	16% (8)	0.340 <sup>b</sup>
Operation time	42 $\pm$ 7 min	35 $\pm$ 6 min	0.624 <sup>(b)</sup>
Blood loss >300 ml	0% (0/52)	0% (0/50)	–
PMR >200 ml	2% (1/52)	12% (6/50)	n.s. <sup>(b)</sup>
Organ injury	0% (0/52)	2% (1/50)	n.s. <sup>(b)</sup>

BMI – body mass index, LAVH – laparoscopic assisted vaginal hysterectomy, VHYE – vaginal hysterectomy, AHYE – abdominal hysterectomy, OAB – overactive bladder, SI – stress incontinence, PMR – post-miction residuum, Chi-square test<sup>b</sup> for qualitative data  $p < 0.05$ , Paired t-test<sup>a</sup> for quantitative data  $p < 0.05$

**Tab. 2. Pelvic organ prolapse quantification measurement at preoperative and postoperative 1-year and 3-year follow-ups according to surgical method (5).**

	preoperative			1-year follow-up			3-year follow-up		
	MESH n=64	ACSSF n=63	P*	MESH n=52	ACSSF N=50	P*	MESH n=48	ACSSF n=45	P*
Aa	2.34±0.6	2.24±0.4	0.346	-1.82±0.7	-1.35±0.8	<b>0.0004</b>	-1.70±0.7	-1.33±1.0	0.051
Ba	2.91±0.7	2.89±0.4	0.897	-2.5±0.8	-1.57±1.3	<b>&lt;0.0001</b>	-2.27±0.9	-1.57±1.4	<b>0.021</b>
C	0.63±1.4	0.61±1.2	0.803	-4.03±1.3	-3.60±1.4	<b>0.457</b>	-3.79±1.0	-3.41±1.0	<b>0.045</b>
Ap	-1.57±0.7	-1.59±0.6	0.861	-1.53±1.3	-1.48±1.1	0.204	-1.33±1.6	-1.68±1.1	0.971
Bp	-2.2±0.7	-2.18±0.7	0.830	-2.04±1.7	-1.77±1.6	<b>0.028</b>	-1.56±2.2	-1.92±1.3	0.229
TVL	9.67±1.0	9.38±0.8	0.123	-1.11±1.2	-1.01±1.2	0.138	-1.10±1.2	-1.00±0.9	0.142

Aa – anterior wall 3 cm from hymen; Ap – posterior wall 3 cm from hymen; Ba – anterior wall, most dependent par (cm); Bp – posterior wall, most dependent par (cm); C – cervix or vaginal cuff (cm); TVL = total vaginal length (cm); \* p-value of Mann-Whitney test

**Tab. 3. Surgical efficacy at 1-year and 3-year follow ups / last carried forward analysis according to surgical method (MESH vs ACSSF).**

	After 1 year			After 3 years		
	MESH	ACSSF	p	MESH	ACSSF	p
POP-Q≤1 (Ba)	<b>92% (48/52)</b>	<b>70% (35/50)</b>	<b>0.004</b>	<b>87% (40/46)</b>	<b>66% (30/45)</b>	<b>0.020</b>
POP-Q≤1 (C)	94% (49/52)	90% (45/50)	0.336	91% (42/46)	80% (36/45)	0.107
LCFA - POP-Q ≤ 1 (Ba)	75 % (48/64)	55 % (35/63)	0,017	63 % (40/64)	47 % (30/63)	0,066
LCFA - POP-Q ≤ 1 (C)	76% (49/64)	71 % (45/63)	0,324	65 % (42/64)	57% (36/63)	0,212

Chi-square test p < 0.05, LCFA – last carried forward analysis

**Tab. 4. Quality of life index at 1-year and 3-year follow-ups.**

	1-year FU			3-year FU		
	MESH	ACSSF	P t-test (t)/Fischer test (FT)	MESH	ACSSF	P t-test (t)/Fischer test (FT)
Subjective	6.63±2.25	6.34±2.45	0.529 (t)	5.98±2.23	6.07±2.27	0.852 (t)
Excellent	44% (23/52)	36% (18/50)	0.777 (FT)	27% (13/48)	20% (9/45)	0.898 (FT)
Very good	25% (13/52)	26% (13/50)		33% (16/48)	38% (17/45)	
Good	25% (13/52)	28% (14/50)		32% (15/48)	33% (15/45)	
Poor	6% (3/52)	10% (5/50)		8% (4/48)	9% (4/45)	

T – t-test, FT – Fischer test, FU– follow-up

past. The average operation time was 42 (± 7) min. The control of patients was scheduled at regular intervals of 6 weeks, 6 months, 1 year and 3 years. In the MESH group, the effectiveness in the anterior compartment (point Ba ≤ -1 cm) at the 1-year follow up was 92 % (48/52), while in the area of the medial compartment (point C ≤ -1 cm) it was 94 % (49/52). At the 3-year follow-up in the latter group we achieved an effectiveness of 87 % in the anterior compartment (point Ba; 40/46), and 91 % in the medial compartment (point C; 42/46).

#### Correction of defect in group with classical ACSSF technique

We assigned 50 women with a combined defect in the anterior (POP-Q – 3) and medial compartments (POP-Q 1–2) to the ACSSF group. The characteristics of the set are presented in Table 1. Hysterectomy was performed on 50 of the women (100 %) in the past, and the average operation time was 36 (± 6) min. At the 1-year follow-up, the effectiveness in the anterior compartment (point Ba ≤ -1 cm) was 70 % (35/50), while that achieved in the area of the medial compartment (point C ≤ -1 cm) was 90 % (45/50). At the 3-year follow-up, the effectiveness achieved in the anterior

compartment was 66 % (point Ba; 30/45), while that achieved in the area of the medial compartment (point C) was 80 % (36/45).

#### Comparison of results from MESH and classic ACSSF technique groups

At the 1-year follow-up, the difference in the effectiveness in the anterior compartment (point Ba) of 92 % achieved in the MESH group (48/52) versus that of 70 % (35/50) achieved in the ACSSF group was statistically significant (p = 0.005). In the area of the medial compartment (point C), the difference between the effectiveness of 94 % (49/52) achieved in the MESH group versus 90 % (45/50) achieved in the ACSSF group was not statistically significant. At the 3-year follow-up, the difference in the effectiveness in the anterior compartment (point Ba) of 87 % (40/46) achieved in the MESH group versus 66 % (30/45) achieved in the ACSSF group was statistically significant (p = 0.021). In the area of the medial compartment (point C), the difference in the effectiveness of 91 % (42/46) achieved in the MESH group versus 80 % (36/45) achieved in the ACSSF group was not statistically significant. We also performed an analysis inclusive of data

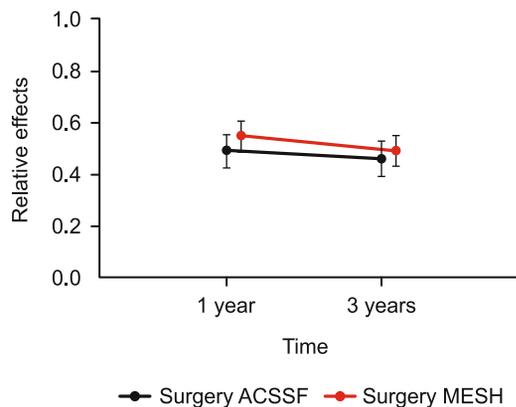


Fig. 2. Relative IQoL satisfaction.

from patients who failed to present for a check-up or deliver the questionnaire (Tab. 3).

### Secondary outcome – IQoL and VAS

At the time of 1-year and 3-year follow-ups, we monitored also the satisfaction with the surgical solution. The patients evaluated their own state on the basis of IQoL and VAS 10. We evaluated the results by using the combination of unpaired t-test and chi-square test at the level of  $p < 0.05$ . At the one-year follow-up, 94 % of patients in the MESH group (49/52) evaluated their own state as minimally good in comparison with 88 % in the ACSSF group (44/50). The difference was not statistically significant. At the 3-year follow-up, 91 % of patients in the MESH group (42/46) were satisfied versus 87 % in the ACSSF group (39/45), and the difference was also not statistically significant. It can be stated that in both groups, the majority of patients were subjectively satisfied with the result of the operation and level of quality of their life (Tab. 4).

We also performed a longitudinal data analysis of IQoL with nonparametric longitudinal data analysis (9). We observed that

there was a nonsignificant difference between MESH and ACSSF, both before and after the surgery ( $p = 0.769$ ). IQoL, however, was significantly lower after surgery in both arms ( $p < 0.001$ ) (Fig. 2).

### Complications with reconstructive POP operations with the use of MESH and ACSSF

We observed also adverse effects and complications of surgery (exposure of synthetic MESH, dyspareunia, overactive bladder, etc.). We also reported a recurrence of prolapse in untreated (posterior) compartment (Tab. 5).

### Discussion

We performed a randomized study on 146 women with a combined defect in anterior and apical compartments after hysterectomy.

Strong points of our study were a) randomisation, b) ensured uniformity of patients assigned to the set as well as that of the type and degree of defect c) uniformity of surgical procedures (every operation was performed by the same surgeon).

In our prospective study, we showed that the effectiveness of the correction of the anterior compartment determined at 1-year and 3-year follow-ups was higher in the MESH group (point Ba: 92 % and 87 %, respectively) in comparison with ACSSF group (point Ba: 70 % and 66 %, respectively). Our results are comparable with those of other studies comparing the effectiveness of correction by use of the synthetic material Elevate anterior or NUVIA SI anterior (10–13).

On the other hand, when we compare the 3-year follow-up results in the medial compartment achieved with MESH (point C: 91%) vs ACSSF (point C: 80 %), the difference is not statistically significant, and the study has shown that the repair of prolapse with the synthetic mesh confers no anatomical benefits to women in the short term (14–16).

However, at a remove of years, we have to state that in line with other studies (17–21), there was a higher risk of a defect occurring *de novo* in the so-called unoperated compartment (in

Tab. 5. Postoperative complications at 1-year and 3-year follow-ups according to surgical method (MESH vs ACSSF)

	1-year FU			3-year FU		
	MESH n=52	ACSSF n=50	p	MESH n=46	ACSSF n=45	p
Mesh exposure	6 % (3)	1 % (1)	0.618	8 % (4)	0 %	0.117
Dyspareunia	10 % (2/21)	9 % (2/23)	1	14 % (3/21)	9 % (2/23)	0.658
OABI	73 % (16/22)	62 % (15/24)	0.539	–	–	–
OAB de novo	6 % (3)	8 % (4)	0.713	–	–	–
SI de novo	11 % (6)	6 % (3)	0.488	–	–	–
RUTC	10 % (5)	6 % (3)	0.716	18 % (9)	8 % (4)	0.230
SI surgery	6 % (3)	4 % (2)	1	–	–	–
RUTC	4 % (2)	2 % (1)	1	4 % (2)	2 % (1)	1
RUTC surgery	0	4 % (2)	0.238	2 % (1)	6 % (3)	0,361
Exposure Surgery	4 % (2)	0	0.495	2 % (1)	0	1
TNO	14 % (7)	10 % (6)	1	8 % (4)	8 % (4)	1

OABI – overactive bladder improvement, SI – stress incontinence, RUTC – relapse in untreated compartment, TNO – total number of operations, FU – follow-up; chi-square test  $p < 0.05$

range of 5–15 %) at 1-year and 3-year follow-ups in the MESH group (5/10 % and 9/18 %, respectively) in comparison with the ACSSF group (3/6 % and 4/8 %, respectively). We ascribe these conclusions to the fact that in case that synthetic material is used, the strength of fixation in the apex of the vagina exerts excessive pressure in the unsupported compartment, thus enhancing the formation of a new defect.

In both groups, at 1-year and 3-year follow-ups, there was observed a lengthening of the vagina as compared to its state before the operation, which may have a positive effect on the quality of sexual life (22, 23, 24). Another monitored modality was the occurrence of complications, which in case that synthetic material is used is one of the main reasons for reclassifying the method from category II to category III, and each patient must be instructed especially regarding the risk of later complications in form of protrusion, origin of chronic pelvic pain, etc. (5, 25).

In the MESH group, protrusions occurred, namely 3 (6 %) at 1-year follow-up and 4 (8 %) at 3-year follow-up. These results are comparable with the results of other studies that used synthetic material (10, 11, 26, 27). In both sets, there was a conformity with other studies (28–30), namely in the significant disappearance of OAB symptoms (MESH 73 % vs ASCCF 62 %); the difference, however, was not statistically significant. Similarly, we also found a lower risk of OAB occurring *de novo* in the MESH group (6 %) as compared to ACSSF group (8 %), and reversely, the occurrence of SI “*de novo*” at 1-year follow-up was higher in the MESH group (11 %) as compared to the ACSSF group (6 %); the difference, however, was not statistically significant. Our findings were similar to those of other studies dealing with the association of the combined defect (anterior/apical) with increased odds of SUI surgery in the future (15, 31–33).

Likewise, we did not find any difference in the duration of hospitalization in the monitored set. Nearly all the patients were released within 48 hours after the operation.

No major loss of blood (higher than 300 ml) occurred in either group and the surrounding organs were injured only once (1x urinary bladder in the ACSSF group). Therefore, in line with other studies, we consider the single-incision mesh technique to be equally safe and at the same time more effective in comparison with classic techniques (11, 26, 34–36).

Our study is in line with other studies (15, 37–39) in showing that at 1-year and 3-year follow-ups, both groups showed a significantly improved quality of life in comparison with that in the preoperative period. We evaluated the index of improvement in the quality of life using VAS where patients from MESH group and ACSSF group assessed their own state as improved, namely in 94 % and 91 % at one-year follow up and 3-year follow up, respectively in the MESH group, and in 88 % and 87 % at one-year follow-up and 3-year follow-up, respectively in the ACSSF group. Our findings were in contrast with other studies that showed that many women reported symptoms that negatively affected their quality of life index (40–43).

In 2013, a register of synthetic implants was established in the Slovak Republic (44). The total number of operations with the use of synthetic material remains stable. However, there is an

increase in the number of laparoscopic/abdominal sacrocolpopexy operations which are becoming the “gold standard” for vaginal prolapse (45–50).

### Learning points

Our study showed that the vaginal synthetic mesh repair of the combined defect in anterior and apical compartments in women after hysterectomy did not improve their outcomes in terms of effectiveness, incidence of SI *de novo*, risk of relapse in the untreated compartment, and numbers of reoperation in the short term.

Despite the results of other studies, the quality of life index in both groups in our study (mesh/classical technique) is evaluated as an improvement.

The strong point of our study is that all patients underwent the surgery conducted at the same workplace and by the same experienced urogynecologist with many years of experience in the given field.

In the future, it will be essential to conduct additional studies with a larger number of respondents (multicentre, prospective) over longer time periods, as recommended by IUGA in 2016. However, in context of current changes (5, 25) and announcements of individual professional societies, it is still questionable whether it would be possible to carry out some form of prospective study in the future.

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