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ORIGINAL ARTICLE

Severe pelvic organ prolapse. Is there a long-term cure?

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Abstract

Introduction and hypothesis Vaginally assisted laparoscopic sacrocolpopexy (VALS) is a combined vaginal and laparoscopic surgical approach that has been described for the treatment of women with a uterus who suffer from severe multicompartmental pelvic organ prolapse (POP). The aim of this study is to evaluate the long-term anatomical and functional outcomes and report the long-term mesh-related complications.

Methods This was a single-center prospective study of women with advanced POP who underwent VALS with at least 3 years of follow-up. The primary outcome was "composite surgical success" defined as: (1) no descent of the vaginal apex (point C) more than one-third into the vaginal canal and no anterior or posterior vaginal wall beyond the hymen (Ba and Bp < 0) (anatomical success), (2) no vaginal bulge symptoms and (3) no re-treatment for prolapse recurrence.

Results The median follow-up was 7 years (range 3–10 years) with a composite surgical success rate of 95.7% (90/94). Failures (4.3%) included one (1.1%) case of anatomical recurrence (Bp: +1), one woman (1.1%) reporting vaginal bulge symptoms and two women (2.1%) who underwent a posterior colporrhaphy 6 and 12 months after primary surgery (reoperation rate: 2.1%). Two of 94 patients (2.1%) had been treated for mesh extrusion of the vaginal cuff prior to the follow-up visit.

Conclusions The combined VALS technique can be considered a safe and effective procedure for the treatment of severe POP allowing a long-term anatomical restoration of all compartments with excellent functional outcomes.

Keywords Pelvic organ prolapse · Sacrocolpopexy · Long-term outcome · Prolapse recurrence · Mesh

Abbreviations

POP	Pelvic organ prolapse
SCP	Sacrocolpopexy
VALS	Vaginally assisted laparoscopic sacrocolpopexy
POP-Q	Pelvic Organ Prolapse quantification system
ICS	International Continence Society
UDS	Multichannel urodynamics
PFDI-20	Pelvic Floor Distress Inventory
PFIQ-7	Pelvic Floor Impact Questionnaire
ICIQ-FLUTS	International Consultation on Incontinence Questionnaire for Evaluating Female Lower Urinary Tract Symptoms
PGI-I	Patient Global Impression of Improvement questionnaire
MUS	Midurethral sling
UIQ-7	Urinary Impact Questionnaire-7
POPIQ-7	Pelvic Organ Prolapse Impact Questionnaire-7
CRAIQ-7	Colorectal-Anal Impact Questionnaire-7
SUI	Stress urinary incontinence
UUI	Urge urinary incontinence

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Introduction

Surgical treatment of women with severe pelvic organ prolapse (POP) represents a major surgical challenge to current urogynecology. In fact, reconstructive surgery for advanced POP has been shown to be associated with a higher risk of developing recurrent prolapse after surgery [1, 2]. It has been hypothesized that severe POP can reflect inherent tissue weaknesses leading to recurrences [3]. Moreover, these patients and

particularly those with severe prolapse of the apical compartment may suffer from multicompartmental defects, which ideally should all be identified and addressed at primary surgery [1, 3].

Surgical treatment of women with severe uterovaginal prolapse includes various transvaginal, abdominal, laparoscopic and robotic approaches, using native tissue or mesh-augmented techniques. In such cases, sacrocolpopexy (SCP) [4] has been shown to be a valid surgical option for the treatment of the apical compartment with or without conservation of the uterus or cervix. Indeed, SCP has been associated with low rates of direct recurrences (prolapse of the apical compartment) [4, 5]. However, when performed alone, SCP does not address all pelvic floor defects [1, 5, 6], leading to indirect recurrences (recurrent prolapse at any other part of the pelvic floor). This highlights the fact that other concomitant procedures might be necessary, inevitably leading to a complex surgical approach.

Vaginally assisted laparoscopic sacrocolpopexy (VALS) [7] is a combined vaginal and laparoscopic surgical approach and has been described for the treatment of women with a uterus who suffer from severe multicompartmental POP. During this procedure, a typical vaginal hysterectomy is initially performed, followed by transvaginal placement of a synthetic mesh on the vaginal walls, which is thereafter suspended laparoscopically on the anterior longitudinal spinal ligament at the S1 level. The vaginal-laparoscopic approach of the VALS technique has been developed to facilitate surgery for such challenging cases as it combines the advantages of each of these approaches, allowing correction of multicompartment pelvic floor defects. In a pilot study [8], VALS has been shown to be both valid and safe with encouraging short-term anatomical and functional outcomes.

Still, the efficacy of a surgical procedure for such complex cases should also be validated in terms of long-term durability, patient satisfaction and impact on the patient's quality of life. In the present study, we sought to evaluate the long-term anatomical and functional outcomes and report the long-term mesh-related complications.

Materials and methods

This was a single-center prospective study of women with advanced POP who underwent VALS at a tertiary referral urogynecology unit between September 2007 and December 2014. The study was given local ethics committee and institutional review board approval, and informed consent was obtained from all patients (date of issue 2 March 2009; registration no. 87). Patients enrolled between September 2007 and March2009 were those included in the previous pilot study [8].

Inclusion criteria were women with multicompartmental symptomatic POP and prolapse of the apical compartment ≥ stage III or IV according to the Pelvic Organ Prolapse quantification system (POP-Q) [9, 10] with at least 36 months of follow-up. Fertile women who have not completed their family and women with severe chronic pulmonary disease, body mass index > 35, previous extensive pelvic or abdominal surgery, organomegaly, ascites, pregnancy and aneurysms were excluded from the study.

Preoperative assessment included objective evaluation of the POP based on the nine-point International Continence Society (ICS) POP-Q system[9] and multichannel urodynamics (UDS). Urinary and pelvic floor symptoms and their impact on the health-related quality of life, daily activities and emotional health were evaluated using the Pelvic Floor Distress Inventory (PFDI-20) [11], Pelvic Floor Impact Questionnaire (PFIQ-7) [11] and International Consultation on Incontinence Questionnaire for Evaluating Female Lower Urinary Tract Symptoms (ICIQ-FLUTS) [12, 13] questionnaires. Postoperatively, all patients were scheduled for a follow-up visit at 3 and 12 months and every 2 years thereafter. For the purposes of the study, all women who underwent a VALS procedure at least 3 years prior to the study period were invited to attend a follow-up visit between September 2017 and January 2018 (study period). The postoperative assessment protocol was identical to the preoperative evaluation, while clinical examination was focused on detecting any mesh-related complications. Postoperatively, all women were also asked to complete the seven-point scale Patient Global Impression of Improvement (PGI-I) questionnaire [14].

The VALS technique has been previously described in detail in a pilot study [8]. A video demonstration of the VALS [7] has also been published and is available online. Briefly, the VALS procedure consists of two steps [8]. Before the first step, a self-adhesive drape is placed at the perineum, while antibiotics are given at induction of anesthesia. The first step is a vaginal approach, which includes the vaginal hysterectomy and transvaginal placement of the mesh on the vaginal walls using monofilament absorbable 2.0 polydioxanone sutures (PDS II, Ethicon/Johnson & Johnson, UK). In all cases a lightweight polypropylene monofilament macroporous non-absorbable mesh (Gynecare Gynemesh PS™ Ethicon, Somerville, NJ/Artisyn Ethicon, Somerville, NJ/Alyte C.R. Bard, Inc., Covington, GA/Upsylon Boston Scientific, Marlborough, MA) was used. Placement of a midurethral sling (MUS) and/or posterior colporrhaphy/perineoplasty was also performed if indicated. The second step consists of a laparoscopic approach during which the meshes are suspended on the anterior longitudinal spinal ligament on S1 level. The cranial aspect of the mesh was secured to the sacral promontory with 5-mm helicoidal titanium tacks (ProTack; Tyco Healthcare, Norwalk, CT, USA) or with a synthetic, monofilament, nonabsorbable polypropylene suture

(Prolene, Ethicon/Johnson & Johnson, UK). The choice of the mesh and anchoring material was based on the local availability. Adhesiolysis and a bilateral salpingo-oophorectomy were also performed in that step if indicated. The procedure is usually conducted under general anesthesia [8]. The authors SA and TG performed all surgical procedures in all cases. Pre- and postoperative findings were collected and registered into the medical record that was specially adapted for the present study patients by authors DZ, AP and EP.

The primary outcome was "composite surgical success" [15], defined as: (1) no descent of the vaginal apex (point C) more than one-third into the vaginal canal [C ≤−(TVL-1/3 TVL)] and no anterior or posterior vaginal wall beyond the hymen (Ba and Bp < 0 (anatomical success), (2) no vaginal bulge symptoms and (3) no re-treatment for prolapse recurrence. Vaginal bulge symptoms were assessed using POPDI question no. 3: "Do you usually have a sensation of bulging or protrusion from the vaginal area?" Secondary outcomes included evaluation of subjective parameters reported by the patients using the PFDI-20, PFIQ-7 and ICIQ-FLUTS questionnaire. Rates of mesh-related complications were identified based on the patient's follow-up records, the patient's response regarding intervention for mesh removal with other healthcare providers and the final follow-up clinical examination during the study period. Mesh extrusion was defined an exposed suture or mesh material in the vagina or other viscera.

Statistical analysis

We used Excel files to create the database including all of the collected data. The normality of the distribution of the impact factors in each year was tested by the Kolmogorov-Smirnov test. If the distribution was normal, we used the mean of the values, if not, we used the median. The distribution for the most part was expected to be non-normal. Therefore, to test the difference between the variables before and after the surgery, we used the Wilcoxon signed-rank test. Statistically significant differences were denoted if the p value of the test was < 0.05. Statistical analyses were performed using SPSS (SPSS v23) and Microsoft Excel [Microsoft (2007), Microsoft Excel (computer software)].

Results

We identified 114 women who underwent VALS at least 36 months prior the study period; 105/114 (92.1%) women were contacted and were invited for the study follow-up visit, while 8/114 (7%) could not be reached with the personal contact data provided and 1 (0.9%) had died of reasons unrelated to the surgery. Of these eight women, 75% (6/8) had undergone the 1-year follow-up visit without any recurrence of the prolapse according to the POP-Q measurements. Of the remaining 105 women, 10.5% (11/105) could not attend the follow-up visit for various personal reasons. All of these 11 patients reported verbally that they did not have any POP symptoms, were satisfied with the surgical intervention and did not have a reoperation related to POP or mesh complications. Demographic characteristics of the study population (94 patients) are presented in Table 1, while the POP preoperative stages of each compartment are presented in Table 2. Additional concomitant procedures included: placement of an MUS in 37 (39.4%), posterior colporrhaphy/perineorrhaphy in 64 (68.1%) and laparoscopic bilateral salpingo-oophorectomy in 54 patients (57.4%) (Table 1). There were no conversions to laparotomy.

The median follow-up was 7 years (range 3–10 years) with a composite surgical success rate of 95.7% (90/94). Failures (4.3%) included: one case (1.1%) of anatomical recurrence (Bp: +1), one woman (1.1%) reporting vaginal bulge symptoms without having anatomic recurrence and two women (2.1%) who underwent a posterior colporrhaphy 6 and 12 months after primary surgery (reoperation rate: 2.1%). These latter cases did not have a posterior colporrhaphy during the primary VALS procedure. At the follow-up visit, no apical or/and anterior recurrence was observed. Preoperative and short- (1 year) and long-term (median 7 years) postoperative anatomical outcomes are shown in Table 3. All POP-Q ICS points showed statistically significant improvement both 1 and 7 years apart from TVL, which remained unchanged.

At the follow-up visit, no cases of mesh extrusion were diagnosed. However, 2/94 patients (2.1%) were treated for mesh extrusion at the vaginal cuff prior to the follow-up visit. Diagnosis occurred in both cases at the clinical examination at

Table 1 Demographics of the study population

	N (%)
Follow-up, median (range)	7 (3–10)
Age, median (range)	56 (41–73)
Parity	
0	0 (0)
1–2	71 (75.5.)
> 2	23 (24.54)
BMI, mean (SD)	24.8 (2.6)
Sexually active	70 (74.5)
Preoperative USI	37 (39.4)
Preoperative DO	14 (14.9)
Type of concomitant surgery	
TVT/TVT-O	37 (39.4)
Posterior colporrhaphy/perineoplasty	64 (68.1)
Bilateral salpingo-oophorectomy	54 (57.4)

SD standard deviation, *BMI* body mass index, *USI* urodynamic stress incontinence, *DO* detrusor overactivity

Table 2 Pelvic organ prolapse preoperative stages of each compartment

Apical prolapse		Concomitant cystocele				Concomitant rectocele			
		St. 1	St. 2	St. 3	St. 4	St. 1	St. 2	St. 3	St. 4
St. 3	52 (55.3%)	0 (0%)	9/52 (11.5%)	46/52 (88.5%)	0 (0%)	15/52 (28.8%)	30/52 (57.7%)	7/52 (13.5%)	0 (0%)
St. 4	42 (44.7%)	0 (0%)	0 (0%)	4/42 (9.5%)	38/42 (90.5%)	0 (0%)	2/42 (4.8%)	5/42 (11.9%)	35/42 (83.3%)

St. Stage

the 1-year follow-up visit. Both patients were successfully treated by transvaginal surgical removal of the extruded part followed by 3-month use of vaginal estrogens. No other surgery was performed for any of the patients because of infection, pain or allergic reaction related to the mesh.

The scores of the PFDI-20 and the PFIQ-7 questionnaires are presented in Table 4. Statistically significant improvements of the PFDI-20 score (91 vs. 202, $p < 0.001$) and of scores of its domains were observed. Statistically significant improvement was also observed in the overall median PFIQ-7 score (52 vs. 2, $p < 0.001$) and the domain of Urinary Impact Questionnaire-7 (UIQ-7) (9 vs. 0, $p < 0.001$) and Pelvic Organ Prolapse Impact Questionnaire-7 (POPIQ-7) (38 vs. 0, $p < 0.001$). No improvement was observed of the Colorectal-Anal Impact Questionnaire-7 (CRAIQ-7). The mean and median values of the ICIQ-FLUTS questionnaire items related to the pre- and postoperative urinary incontinence symptoms are presented in Table 5. Statistically significant improvements ($p < 0.001$) of the mean and median values of the "frequency," "urgency" and "stress urinary incontinence" (SUI) symptoms were observed. On the contrary, mean and median values of the "urge urinary incontinence" (UUI) symptoms had no statistically significant variation.

According to the PGI-I scale, all women reported improvement in their condition; 75/94 (79.8%) reported being "very much better," while 12 (12.8%) and 7 (7.4%) reported being "much better" and "better," respectively. None of the patients described their condition as "unchanged" or "worse."

Discussion

The present study provides evidence regarding the long-term efficacy of the VALS in treating women with severe POP. The study showed that after a median follow-up of 7 years, VALS provided excellent rates of anatomical support, symptomatic relief and patient satisfaction with low rates of vaginal extrusion.

The interpretation of the postoperative anatomical results should consider that the study population included patients suffering from severe POP (median value of point C was +6) (Table 2). Previously published studies on laparoscopic SCP included women with less advanced POP [2, 16–18]. We consider this observation important for surgical planning as it has been shown that preoperative POP stage III or IV is a significant risk factor for prolapse recurrence after surgery [1]. The study population also included women with low median age (56 years), which has also been found to be an important risk factor for POP recurrences. In fact, according to two studies [19, 20] younger age (below 60 years) was found to be a risk factor for POP recurrence after surgery compared with older women. It appears therefore that even for patients having risk factors for POP recurrence, this combined vaginal-laparoscopic approach offers excellent long-term anatomical outcomes.

Furthermore, women who present with severe POP are more likely to have defects that involve various levels of pelvic support [3]. SCP is an operation primarily designed to

Table 3 Short- (1 year) and long-term (median 7 years) anatomical outcomes of the VALS according to POP-Q system

POP-Q	Preoperatively ($N = 94$)		Postoperatively (1 year) ($N = 94$)		*p* value	Postoperatively (> 3 years) ($N = 94$)		*p* value
	Median (range)	Mean (SD)	Median (range)	Mean (SD)		Median (range)	Mean (SD)	
Aa	2.5 (−2 to 3)	2 (1.2)	−3 (−3 to −1)	−2.7 (0.5)	**< 0.001**	−2.5 (−3 to −1)	−2.5 (0.8)	**< 0.001**
Ba	5 (−1 to 10)	5 (2.1)	−3 (−3 to −1)	−2.7 (0.4)	**< 0.001**	−2.4 (−3 to −1)	−2.3 (0.7)	**< 0.001**
Ap	−0.5 (−2.5 to 3)	−0.5 (1.6)	−3 (−3 to −2)	−2.8 (0.3)	**< 0.001**	−3.0 (−3 to −1)	−2.7 (0.5)	**< 0.001**
Bp	0 (−2.5 to 10)	1.2 (3.2)	−3 (−3 to 1.5)	−2.8 (0.3)	**< 0.001**	−3 (−3 to 1)	−2.5 (0.5)	**< 0.001**
C	6 (1.5 to 11)	5.5 (2.7)	−8.5 (−12 to −6)	−8.6 (0.9)	**< 0.001**	−8 (−12 to −5)	−8.3 (1.3)	**< 0.001**
TVL	9 (6 to 12)	9.3 (1)	9 (7 to 12)	9.2 (1.3)	0.284	9.0 (7 to 12)	9.1 (1.3)	0.153
GH	4.5 (2 to 7)	4.3 (0.9)	3 (1.5 to 7)	3.2 (1.2)	**< 0.001**	3 (1.5 to 7)	3.2 (1.2)	**< 0.001**
PB	3 (2 to 4)	2.9 (0.6)	3 (2 to 4)	3.1 (0.5)	**0.004**	3 (2 to 4)	3.1 (0.5)	**0.004**

VALS vaginally assisted laparoscopic sacrocolpopexy, *POP-Q* Pelvic Organ Prolapse quantification system

Table 4 Impact of VALS on pelvic floor symptoms and health-related quality of life based on the median and mean values of the PFDI-20 and PFIQ7 questionnaire

	Pre		Post		P
	Median (range)	Mean (SD)	Median (range)	Mean (SD)	
POPDI6	50 (0–100)	46.7 ± 23.3	4 (0–41)	5.8 ± 8.3	**< 0.001**
CRADI8	12 (0–75)	15.8 ± 13.3	6 (0–50)	12.7 ± 12.7	**0.044**
UDI6	25 (0–75)	27.7 ± 20.1	8 (0–66)	11.6 ± 15	**< 0.001**
PFDI-20	91 (0–216)	90.3 ± 44.7	20 (0–138)	30.1 ± 27.5	**< 0.001**
UIQ7	9 (0–100)	19.9 ± 26.6	0 (0–100)	8.0 ± 15.8	**< 0.001**
CRAIQ7	0 (0–100)	4.0 ± 13.7	0 (0–61)	5 ± 11.5	0.201
POPIQ7	38 (0–18)	40.6 ± 31.5	0 (0–19)	0.7 ± 2.5	**< 0.001**
PFIQ7	52 (0–300)	64.6 ± 56.4	2 (0–141)	13.7 ± 23.2	**< 0.001**

VALS vaginally assisted laparoscopic sacrocolpopexy, *PFDI-20* Pelvic Floor Distress Inventory, *PFIQ-7* Pelvic Floor Impact Questionnaire

address level I pelvic support defects but when performed as a single operation has been shown to be less effective for the treatment of the anterior and posterior compartment with failure rates as high as 62 and 44%, respectively [2, 5, 6]. Therefore, in cases with severe POP other concomitant procedures at the time of SCP seem to be necessary for addressing level II and level III pelvic floor defects [2]. The results of our study confirmed that the combined technique addressed effectively not only the apical, but also the concomitant anterior and/or posterior vaginal wall defects at various levels, minimizing both direct and indirect recurrences.

The role of the location of the mesh after SCP on the anterior and posterior compartment in relation to POP recurrence has been investigated in a study by Wong et al. [5]. The authors suggested that prolapse recurrence seemed to be related to the mesh position and that for every millimeter that the mesh was located further from the bladder neck on Valsalva, the likelihood of cystocele recurrence increased by 6–7%. This highlights the importance of performing deep caudal dissection of the anterior and posterior vaginal wall, which is often required for optimal mesh placement. However, manipulations and suturing in the deep pelvis are often limited by poor tissue-plane separation and bleeding [5] leading to a more proximal and therefore suboptimal placement of the mesh. The advantage of the initial vaginal approach of the VALS [7, 8] is that it facilitates distal dissections of both the rectovaginal and pubocervical fascias down to the mid-vagina and to the urethrovaginal junction, respectively. Moreover, the transvaginal approach permits dissections that can be extended laterally up to the vaginal sulci, omitting the need to perform any vaginal or laparoscopic paravaginal repairs.

Concerns have been raised regarding vaginal placement of the mesh during SCP. The reported incidence of the mesh-related complications, including mesh extrusion, in patients undergoing laparoscopic SCP with the use of macroporous soft polypropylene mesh, with or without concurrent hysterectomy, is up to 3.4% [21]. It has been suggested that this rate was significantly increased in cases of vaginal insertion of the mesh (40%) [22]. In the present study, the erosion rate was only 2.1%, and no other infective complications were observed. The low extrusion rate observed in the study population might be due to the surgical steps of this procedure. First, the transvaginal steps permit easier tissue dissections, which are performed at the right depth because of the direct visual and haptic feedback during dissections. This allows the meshes to be sutured onto a thick vaginal wall including the pubocervical and the rectovaginal fascias. Moreover, the sutures can be easily placed away from the devascularized vaginal cuff, thus minimizing the risk of extrusion at this level.

It has also been suggested that mesh extrusion may be the result of an inflammatory reaction due to a previous mesh infection. However, a recent study [23] showed that transvaginal placement of the mesh was not related to MRI changes suggesting mesh infection or mesh dehiscence in the early (3-month) and

Table 5 Pre- and postoperative median and mean values of the ICIQ-FLUTS questionnaire items related to urinary incontinence symptoms

	Pre		Post		*P**
	Median (range)	Mean (SD)	Median (range)	Mean (SD)	
Frequency (Fluts 2)	1 (0–4)	1 ± 1.2	1 (0–4)	0.7 ± 0.8	**0.009**
Urgency (Fluts 3)	1 (0–4)	1.1 ± 1.2	0 (0–4)	0.5 ± 0.9	**< 0.001**
UUI (Fluts 9)	1 (0–4)	1.3 ± 1.4	0 (0–4)	2.4 ± 14.3	0.059
SUI (Fluts 11)	0 (0–4)	0.7 ± 0.9	0 (0–4)	2.5 ± 14.3	**< 0.001**

ICIQ_FLUTS International Consultation on Incontinence Questionnaire for Evaluating Female Lower Urinary Tract Symptoms, *UUI* urge urinary incontinence, *SUI* stress urinary incontinence

mid-term (12-month) postoperative period. It can be hypothesized that the prophylactic steps taken to minimize bacterial contamination during surgery, such as the use of a self-adhesive perineal drape, antibiotic prophylaxis at the induction of anesthesia and minimization of mesh manipulations during suturing, may also play an important role. Similar results were also reported by a controlled study performed by Nosti et al. [24]. In this study, the rate of mesh complications among women who underwent vaginal mesh attachment at the time of total vaginal hysterectomy with laparoscopic SCP compared with women undergoing laparoscopic mesh attachment at the time of laparoscopic supracervical hysterectomy and SCP was similar [1.6% (2/123) vs. 1.7% (1/59); $P = 1.0$]. A similar extrusion rate (2.3%) was also reported by another study [25] where 44 patients underwent VALS for severe POP. It seems, therefore, that vaginal placement of the mesh may be a safe option if the surgical procedure meets the basic aseptic and antiseptic rules.

We acknowledge that the major limitations of this study are its single-center design and the absence of a control group. Moreover, sexual function was not assessed after surgery. Nevertheless, the fact that all data were prospectively collected following a predefined follow-up protocol and recorded in an electronic database specially developed for urogynecology patients with a very low drop-out rate (10.5%) minimizes the risk of bias. Contrarily, this study has several strong points such as the large number of patients with such severe POP, which is the largest reported so far in the literature concerning long-term anatomical and functional outcomes after treatment with the combined technique or laparoscopic SCP. Moreover, the fact that pre- and postoperative assessment of all patients was performed using validated condition-specific tools minimizes the risk of evaluation bias. Finally, the presentation of long-term anatomical and functional outcomes according to the IUGA and ICS joint report [26] enhances the power of the study regarding the safety of this surgical technique.

In conclusion, the combined VALS technique can be considered a safe and effective procedure for the treatment of severe POP allowing a long-term anatomical restoration of all compartments with excellent functional outcomes. Future randomized controlled trials may evaluate the long-term effectiveness of VALS compared with other surgical techniques such as laparoscopic SCP to provide guidance for the surgical management of women with advanced POP.

Compliance with ethical standards

Conflicts of interest None.

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