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ORIGINAL ARTICLE

Sacrocolpopexy for posthysterectomy vaginal vault prolapse: long-term follow-up

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Abstract
Introduction and hypothesis Abdominal sacrocolpopexy (ASC) is considered the gold standard for vaginal vault prolapse (VVP) repair. Our aim was to evaluate the long-term durability of its anatomic and functional results.
Methods This was a prospective series of women undergoing ASC for symptomatic VVP stage III or IV according to the Pelvic Organ Prolapse Quantification (POP-Q) system. All patients were followed up every 3 months for the first postoperative year and then annually for anatomical and functional outcomes and complications. Only patients with at least 48 months of follow-up were included in this report. Anatomic success was defined as postoperative prolapse stage 0 or I. Statistical analysis was performed using the nonparametric Mann–Whitney *U* test for the analysis of continuous variables and the McNemar and χ^2 test for categorical data.
Results Sixty-seven women were followed up for a median of 60 months (range 48–144). Anatomical success was 100 % for apical prolapse and 94 and 91 % for anterior and posterior compartments, respectively. There were only four (6 %) and six (9 %) cases of stage II persistence or recurrence for the anterior and posterior compartments, respectively, which did not require reoperation. There was no vault prolapse recurrence. Voiding and storage urinary and sexual symptoms were significantly improved. Anorectal dysfunction symptoms persisted in 40.6 % of patients with these symptoms preoperatively and developed de novo in 22.8 % of patients without them preoperatively. Three mesh exposures were noted. Sixty-three patients (94 %) were extremely or very much improved with sacrocolpopexy according to the Patient Global Impression–Improvement scale.
Conclusions Our data confirm the long-term durability of vaginal vault prolapse repair with ASC.

Keywords Anatomical outcomes · Functional outcomes · Long-term · Sacrocolpopexy · Safety · Vaginal vault prolapse

Introduction

Pelvic organ prolapse (POP) is an increasingly common female health problem: it is estimated that the number of affected women will increase by 46 % from 3.3 million in 2010 to 4.9 million in 2050 in the United States [1]. Symptomatic POP has a significant, negative impact on all aspects of daily life [2]. Therefore, treatments should restore anatomy and alleviate symptoms, thus improving overall patient quality of life (QoL) over the long term. The joint International Urogynecological Association (IUGA) and International Continence Society (ICS) report defined vaginal vault prolapse (VVP) as the observation of descent of the vaginal vault (cuff scar) after hysterectomy [3]. Several surgical options for its correction exist: abdominal sacrocolpopexy (ASC) is an effective procedure [4], at least in the short- and intermediate-term follow-up, but its long-term outcomes have not been adequately evaluated. The aim of this study was to evaluate the long-term anatomic and functional outcomes and patient satisfaction in a group of women who underwent open abdominal sacrocolpopexy for posthysterectomy VVP.

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Materials and methods

This was a single-center prospective series of women who underwent open abdominal sacrocolpopexy (ASC) for symptomatic VVP. The local ethics committee approved the study, and patients signed an informed consent document. Adult women with symptomatic stage III or IV VVP according to the Pelvic Organ Prolapse Quantification (POP-Q) system [5 who opted for ASC were enrolled. Patients with a minimum of 48 months follow-up were evaluated.

All patients were preoperatively assessed using a standardized protocol. Evaluations included medical and urogynecological history, clinical urogynecologic examination, uroflowmetry with postvoid residual (PVR) measurement, and urodynamic testing. Demographic data, menopause, hormone replacement therapy status, and previous prolapse and/or incontinence surgery were collected. Diagnosis of urinary symptoms, anorectal dysfunction symptoms, and sexual dysfunctions was made my means of clinical history according to current recommendations [5] as the study evolved: when updated terminology standards were available [3, 6] they were adopted for patient evaluation. From 2010 onward, the joint IUGA/ICS terminology report definitions [3] were applied in both preoperative and follow-up assessments and are used in this report. POP was quantified according to the POP-Q system [5]. Symptoms and their impact on patients' QoL were further assessed using validated questionnaires. The short forms of Incontinence Impact Questionnaire (IIQ-7) and Urinary Distress Inventory (UDI-6) [7] were administered for urinary symptoms, including incontinence. The Female Sexual Function Index (FSFI) [8] was used to assess sexual function from 2000, when it was published, onward. A simple translation of the questionnaires was initially used until language-validated versions became available [9].

All surgical procedures were performed by two senior surgeons (EC, A Z). The anterior vaginal wall was dissected from the bladder down to the bladder neck to expose a large vaginal wall area where a rectangular macroporous, monofilament polypropylene mesh (Cousin Biotech®) was attached with four polyglycolic 1–0 sutures. The dissection was repeated for the posterior vaginal wall, which was prepared down to the levator ani plane. Another rectangular polypropylene mesh was attached to the posterior vaginal wall with four polyglycolic 1–0 sutures, avoiding the levator ani. The sacral promontory surface was prepared. A subperitoneal tunnel was created from the sacrum to the vaginal vault, through which both meshes were passed and fixed at the level of the sacral promontory, lateral to the midline to avoid the medial sacral artery. Fixation to the sacrum was done with one or two nonabsorbable, monofilament polypropylene 2.0 sutures, avoiding tension.

The performance of concomitant Burch colposuspension was the patient's decision: women were informed on the uncertainty in the literature regarding selection of patients that would benefit most from a concomitant anti-incontinence procedure either for preoperatively evident stress urinary incontinence (SUI) or as a prophylactic measure for the development of de novo incontinence. They were also given the option, according to our local practice, to follow a two-step approach with performance of anti-incontinence procedure in case SUI persisted or became evident at a later time after prolapse repair. When patients opted for an anti-incontinence procedure, Burch was the only option offered given the interest in this procedure because of the concurrent Colpopexy and Urinary Reduction Effort (CARE) trial [10]. No other concomitant procedures were performed. Patients were followed up at 1, 3, 6, and 12 months postoperatively and thereafter annually, using the rigorous preoperative protocol with the exception of urodynamic testing, which was not performed postoperatively. Furthermore, complications were recorded according to the Clavion–Dindo classification of surgical complications [11, 12], and patients' perceptions of the overall outcome were evaluated with the self-administered Patient Global Impression Improvement questionnaire (PGI-I) [13].

Anatomic success was defined as postoperative prolapse stage 0 or I, according to the POP-Q. Failure to correct to normal support (stage 0 or I) was considered persistence of prolapse following initial correction and return to a higher stage was considered a recurrence. As far as symptoms are concerned, their presence, at any postoperative follow-up, in a patient with the same symptoms as preoperatively, was considered persistence. Complaints of symptoms not recorded preoperatively were considered as de novo cases.

For a comprehensive evaluation of success of ASC, we calculated the Satisfaction–Anatomy–Continence–Safety (SACS) score [14], which incorporates four major POP surgery outcomes in a single value: Patient satisfaction, POP quantification, Continence, and Safety. A maximum score of 4 represents a "cure". Due to asymmetric distribution of data evaluated by the Shapiro-Wilk test, statistical analysis was performed using the nonparametric Mann–Whitney U test for the analysis of paired and unpaired continuous variables and the McNemar and χ^2 tests for paired and unpaired categorical data, respectively. All calculations were performed using IBM-SPSS® version 22.0 (IBM Corp., Armonk, NY, USA, 2013). A two-sided p value < 0.05 was considered significant. Values are presented as median [interquartile range (IQR)] or number (percentage).

Results

From June 1996 to May 2011, 73 consecutive patients underwent ASC for VVP, stage III or IV. Five patients were lost to their 48-month follow-up, and one passed away 3 years postsurgery; the remaining 67 are included in this report.

Median follow-up was 60 months (range 48–144 months). Table 1 shows baseline demographic information and clinical characteristics of the study population.

Apical prolapse was corrected to stage 0 in all patients (100 %) without cases of persistent or recurrent prolapse. Anatomical correction success rates for the anterior and posterior vaginal compartments were 94 and 91 %, respectively. There was one case of persistent stage II anterior compartment prolapse and three of recurrent stage II anterior compartment prolapse. In the posterior compartment, there were four and two cases of stage II persistence and recurrence, respectively. Figure 1 shows the distribution of prolapse stages at baseline and last follow-up for the anterior and posterior vaginal compartments. All cases of persistent or recurrent stage II prolapse were asymptomatic. They were evident in the first 6 months of follow-up and remained stable thereafter. No patient required reoperation for prolapse symptoms.

Overall urinary symptoms were significantly improved at follow-up compared with baseline. This is reflected in a significant decrease in UDI-6 and IIQ-7 scores from a median (range) of 4 (0–18) and 5 (0–21) at baseline, respectively, to 2 (0–11) and 2 (0–21) at follow-up ($p < 0.001$). Storage symptoms were present in 48 of the 67 patients (71.6 %) at baseline. In the first postoperative months, they disappeared in 41 of 48 patients (85.4 %), persisted in seven (14.6 %), and appeared de novo in one. At 1-year follow-up, there was a slight increase in storage symptoms prevalence (from 11.9 to 17.9 % of the total study population) due to four de novo cases of nocturia. Thereafter, there was a 25 % spontaneous resolution resulting in only nine patients with storage symptoms at the 48-month follow-up. After 4 years, only one de novo case emerged. The time trend for storage symptoms is shown in Fig. 2. Only one of eight patients with storage symptoms in the first postoperative months had detrusor overactivity at baseline urodynamics, in comparison with four of nine in the long-term follow-up.

Voiding symptoms were present in 61 patients (91 %) at baseline, persisting only in three in the first months after surgery. These three cases underwent contemporary Burch colposuspension and had detrusor underactivity at baseline urodynamics. De novo voiding symptoms were reported by one patient at 1-year follow-up; no cases of de novo voiding symptoms appeared thereafter (Fig. 2). The significant improvement in voiding symptoms is reflected in a significant improvement in maximum urinary flow rate from a median of 12.0 (7.0– 19.9) ml/s at baseline to 25.0 (16.9– 32.3) at long-term follow-up ($p = 0.001$).

Before sacrocolpopexy, 39 patients (58.2 %) were incontinent, 12 (17.9 %) had urgency or predominantly urgency incontinence, and 27 (40.3 %) had stress or predominantly stress UI. Urge incontinence disappeared in all but three of the 12 patients within the first postoperative year; for two of them, there was spontaneous resolution by the second-year visit, and the third responded well anticholinergic therapy. SUI persisted in 13 of 27 patients in the first postoperative months, during which time one de novo case occurred. During the first 2 years, five of these patients showed a spontaneous improvement. but two more de novo cases emerged. All three de novo cases appeared in patients that did not have Burch colposuspension. After the second year, there were no new cases of SUI. In total, three patients opted for anti-incontinence (TVT or adjustable continence treatment) surgery. The remaining patients were not bothered by SUI or were treated conservatively with pelvic floor muscle training.

Fifteen patients in our study population underwent concomitant Burch colposuspension: 12 due to preoperative SUI (8 for stress or predominantly SUI and four for the stress component of predominantly urgency, mixed incontinence) and three as prophylactic measure. Among 12 patients who underwent concomitant Burch colposuspension because of SUI, SUI persisted in five (41.7 %) immediately after surgery, of whom one patient showed a spontaneous improvement and one underwent further anti-incontinence surgery. The remaining patients were treated conservatively. No patient with prophylactic concomitant Burch colposuspension developed de novo incontinence.

Anorectal dysfunction symptoms were present preoperatively in 32 patients (47.8 %), persisted in 13 (40.6 %) after surgery, and presented de novo in eight, resulting in a nonsignificant overall change. One patient with persistent symptoms

Table 1 Preoperative characteristics of the study population

	Study group ($n = 67$)
Age (years) median (IQR)	67.2 (60.1–72.1)
Body mass index (kg/m^2), median (IQR)	26.2 (24.1–29.0)
Parity (median, range)	2 (1–4)
Baby's birth weight (g), median (IQR)]	3650 (3300–4000)
Menopause (*n*, %)	67 (100)
Hormone replacement therapy (*n*, %)	6 (9)
Previous prolapse or continence surgery (*n*, %)	38 (56.7)
Previous Burch colposuspension (*n*, %)	7 (10.4)
History of recurrent urinary tract infections (*n*, %)	3 (4.5)
Anxiety-depression syndrome	19 (28.3)
Hypertension (*n*, %)	31 (46.2)
Diabetes (*n*, %)	2 (3)
Thyroid disorders (*n*, %)	10 (14.9)
Voiding symptoms (*n*, %)	61 (91.0)
Storage symptoms (*n*, %)	48 (71.6)
Sexually active (*n*, %)	32 (47.7)
Sexual dysfunction (*n*, % of sexually active)	17 (53.1)
Anorectal dysfunction symptoms (*n*, %)	32 (47.8)
Stress or predominantly stress incontinence (*n*, %)	27 (40.3)
Urge incontinence (*n*, %)	12 (17.9)

IQR interquartile range

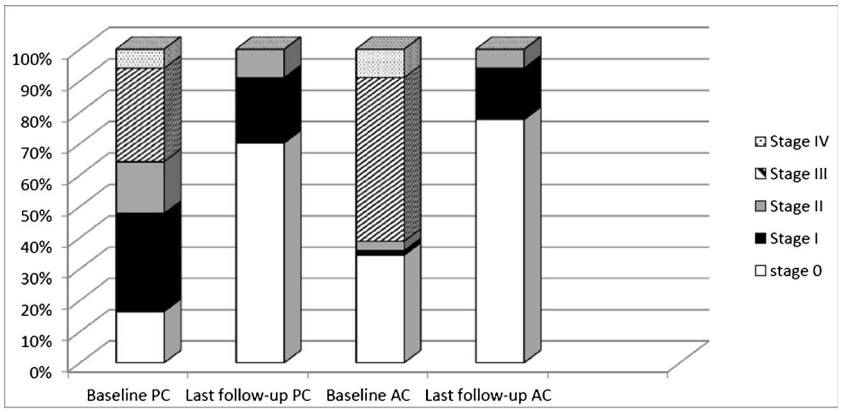

Fig. 1 Distribution of anterior and posterior compartment prolapse stages at baseline and follow-up

underwent colorectal surgery for obstructed defecation. De novo symptoms were mild (constipation and feeling of incomplete evacuation) and were treated conservatively. There were no cases of painful defecation.

Thirty-two (47.7 %) patients were sexually active at baseline. After surgery, two of 35 patients previously not sexually active resumed their sexual activity. Before surgery, sexual dysfunctions were present in 17 (53.1 %) of sexually active patients and improved in seven (41.2 %) with sacrocolpopexy ($p = 0.001$). FSFI score showed a statistical improvement from a median of 4 (2.0–22.5) at baseline to 18.5 (2.3–25.1) at follow-up ($p < 0.001$). De novo sexual disorders developed in three patients within the first 2 postoperative years; one was due to mesh exposure.

According to the Clavion–Dindo classification, there were seven (10.4 %) grade 1 and three grade 2 complications. Grade 1 were fever (4), wound infection (1), and constipation (2); grade 2 were blood transfusion (2) and paralytic ileus requiring temporary placement of a nasogastric tube (1). The average blood loss was 118.28 ml. Three mesh exposure cases (grade 3, 4 %) were recorded at 1, 6, and 24 months after ASC; all underwent vaginal mesh revision. There were no complications of grade 4 or 5 or of intraoperative bladder, vaginal, bowel trauma, sepsis, osteitis, or discitis.

According to the SACS scoring system, 57 patients (85.1 %) reached the maximum score of 4 at median 60-month follow-up and were considered "cured". Sixty-three patients (94 %) were extremely or very much improved according to the PGI-I scale.

Discussion

Our study results confirm that abdominal sacrocolpopexy is an excellent surgical option for posthysterectomy VVP repair. Stage III and IV vault prolapse was reduced to stage 0 in all patients without any persistent or recurrent prolapse at a median follow-up of 60 months. The anatomical success rates for the anterior and posterior compartments were 94 and 91 %, respectively. All cases of stage II persistence or recurrence were asymptomatic and no reoperation was required. Voiding urinary symptoms were almost eliminated, but overall anorectal dysfunction symptom improvement was not completely satisfactory, as there were both persistent and de novo cases. The prevalence of postoperative incontinence and other storage symptoms, after minor fluctuations in the first 2 years, settled in steadily low figures.

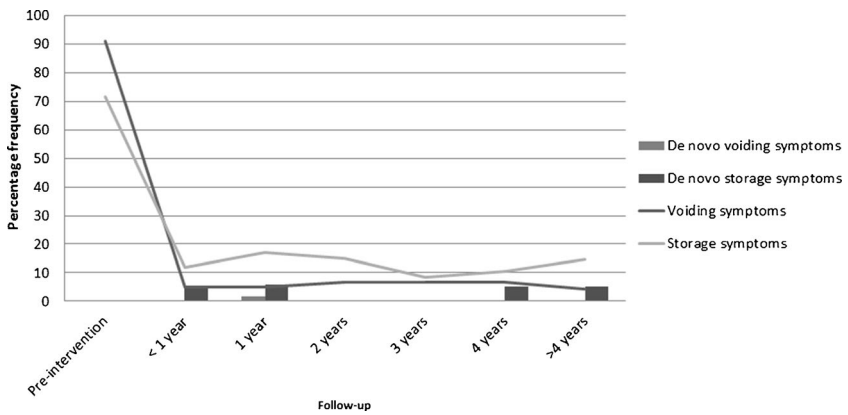

Fig. 2 The time trend curve of urinary symptoms

Despite the abundance in the literature of studies reporting on the efficacy and safety of sacrocolpopexy, comparisons of data between studies and extrapolation of results is not straightforward. Reasons are the diversity in patient inclusion criteria, variation in surgical technique used, differences in the duration of follow-up and—most importantly—substantial heterogeneity of outcome measures.

Anatomic prolapse correction rates observed in our study are within the range found in the literature [15], where success is commonly higher when only apical correction is considered, and spans from 78 to 100 %. No patient in our population required reoperation for prolapse. The need for reoperation for recurrent prolapse ranges from as low as 0, as in the case of our study, to as high as 18.2 % [15]. In our experience, anatomic correction achieved with sacrocolpopexy was durable over time, with no recurrences at a minimum of 48 and maximum 144 months follow-up. Interestingly, papers in the literature reporting on long-term anatomic correction with sacrocolpopexy are sparse. Similar to our study, a retrospective study of 57 Korean women [16] reported success rates of 100 % for apical and 86 % for any vaginal compartment at a follow-up of at least 60 months (range 60–108). These results are somewhat contradicted by the-long term results of the extended CARE trial [17], which was a multicenter, masked trial in which 322 women without SUI undergoing abdominal sacrocolpopexy for POP were randomized to have concomitant prophylactic Burch colposuspension or not. In their long-term results authors of the extended CARE trial reported that anatomical failure increased from 8.9 % (13 of 145 patients) at 2 years to 19.8 % (22 of 111 patients) at 4 years and 42.4 % (31 of 73 patients) at 7 years. The reasons for this finding cannot be established with certainty. One possible explanation is the study's multicenter nature, which led to a significant loss of participants in the long-term follow-up, thus possibly introducing selection bias: only 90 of the 322 originally randomized patients were available for physical examination at 7 years. The single-center nature of our study has worked as an advantage in this respect, allowing long-term, in-person evaluation of our patients. Another explanation for the high sacrocolpopexy failure rates in the extended CARE trial may be the lack of standardized surgical technique: a variety of mesh configurations and materials (biological, Mersilene, polypropylene, and Gore-Tex®) and a diversity of types and number of sutures to fix the mesh were used, at the surgeon's discretion. Supporting our argument is evidence from other trials with long-term follow-up showing that outcomes are technique dependent: for example, objective anatomic success rates at 5 years are 93 % with polypropylene mesh compared with 62 % with cadaveric fascia lata [18]. In our series, the technique is highly standardized, as described in "Materials and methods". Even though high-quality evidence on the importance of specific surgical aspects is lacking, we strongly believe that their effect in both short- and long-term outcomes is crucial. In particular, a wide preparation of vaginal walls with mesh attachment to their entire length, not simply to the vaginal apex, is of utmost importance. Our previous experience [19] suggests a high rate of prolapse recurrence in the anterior compartment when the anterior vaginal wall is not widely dissected and supported by mesh inlay.

In our study, urinary symptoms were overall significantly improved with sacrocolpopexy. Voiding symptoms disappeared in 95.1 % of patients immediately postoperatively, and flow rates increased significantly. This was not a surprise, as the distortion of anatomy in cases of prolapse has been associated with voiding symptoms, low urinary flow rates, and other urodynamic abnormalities [20]. The persistence of voiding difficulty in three patients may be explained by the observation of detrusor underactivity during preoperative urodynamics. Storage symptoms persisted in 14.6 % of our population during the first postoperative months, and the prevalence slightly increased at 1 year follow-up but then subsided spontaneously in a quarter of cases and settled to a low and steady prevalence after the second postoperative year. The pathophysiology of storage symptoms is multifactorial in women with prolapse, and persistence and de novo cases are expected after prolapse treatment [20].

Urge incontinence disappeared in all but three of the 12 patients with preoperative predominantly UI. This is in accordance with other studies reporting urge incontinence resolution of 63 % after the surgical repair of apical prolapse [21].

More complex is the issue of SUI. Complexities begin with the definition of this population, which may be done in terms of patient symptoms, physical examination with a cough stress test or urodynamic testing, with or without prolapse reduction, to unmask occult incontinence. In our population, 27 women had symptoms of stress or predominantly SUI. Symptoms were cured in half of them and persisted in 13. One patient, preoperatively continent, developed de novo SUI in the first months after surgery. Two more de novo cases were observed at 2-year follow-up, without further changes thereafter.

Among the 12 patients who underwent concomitant Burch colposuspension because of SUI or the SUI component of predominantly urgency incontinence, SUI persisted in five (41.7 %) immediately after surgery. This is in accordance with our previous experience [22], in which 56.5 % of SUI women undergoing POP repair and concomitant colposuspension in a randomized trial remained incontinent postoperatively. The reason for this observation has not been adequately investigated. Our data suggest that Burch colposuspension may be an inadequate treatment for evident SUI in patients having sacrocolpopexy for prolapse.

In this study, none of our patients who underwent prophylactic Burch colposuspension developed de novo SUI. Three of the 25 continent patients who did not have Burch colposuspension developed de novo SUI, a percentage higher than expected in our experience. The small sample size may

be an explanation for this observation. The performance of prophylactic anti-incontinence procedures in women with SUI remains somewhat controversial. In our previous experience [23], not only prophylactic procedures failed to improve continence outcomes but also were associated with a higher postoperative incontinence rate (26.5 vs 3.1 % in patients without concomitant procedures), suggesting even a harmful effect. In contrast, the CARE trial [22] showed that Burch colposuspension significantly reduces postoperative symptoms of SUI. In a systematic review of available trials, the benefit of concomitant anti-incontinence procedures in symptomatically continent women seems to be marginal and not statistically significant [24].

To further contradict our study findings, which suggest stability of incontinence outcomes over time, the extended CARE study [17], similarly to deterioration in anatomical outcomes, reported an increase of SUI treatment failure rates with long-term follow-up. Reasons for that are probably the same with those of anatomic failure, which have already been discussed.

In any case, there are no factors that could safely predict incontinence outcomes in patients operated for POP. Therefore, patients have to make an informed decision on either having a concomitant anti-incontinence operation or wait for the results of their POP repair first. Our preference for the second option is justified by the low reoperation rate for postoperative SUI in our series.

As far as anorectal dysfunction symptoms are concerned, in our study, they disappeared in 19 patients but persisted in 13 and appeared de novo in eight, resulting in an overall insignificant change. This is similar to other studies in the literature [25–27]. The diversity of effects of sacrocolpopexy on anorectal dysfunction symptoms has been attributed to several different mechanisms: elevation of the posterior wall may alleviate obstruction related to severe posterior compartment prolapse, extensive preparation in the pouch of Douglas, and fixation of the posterior mesh to the levator ani plane may cause bowel dysfunction and de novo symptoms such as painful defecation, and symptoms may be independent of the prolapse and the result of the effects of other comorbidities.

Another finding in our study was the overall improvement of sexual dysfunction. This is accordance with our previous experience [28]. In contrast to other studies [27] reporting de novo dyspareunia at long-term follow-up, no such cases were observed in our series. Factors other than prolapse that may lead to female sexual dysfunction, including advancing age, vaginal atrophy, comorbidities, and sexual dysfunction of the partner, should be taken into consideration when long-term sexual outcomes of sacrocolpopexy are reported.

As sacrocolpopexy is a reconstructive procedure, not only anatomy but also function of prolapsed organs should be restored. Nevertheless, patients' satisfaction with the procedure does not depend only on anatomic and functional outcomes but the tolerability of the procedure and its impact on overall patients' QoL. For this reason, we also assessed the overall success of sacrocolpopexy using the SACS score, which incorporates different outcomes and patient perceptions. A maximum score of 4 was reached by 85 % of our patients at a median 60-month follow-up, reflecting high efficacy; mild, well tolerated complications; and satisfied patients. Our findings are in line with evidence in the literature [15] regarding complications, especially mesh exposure, and impact on QoL. One of our mesh exposure cases was found during the fist-month follow-up. Whether this early exposure represents an unrecognized intraoperative vaginal injury cannot be assessed.

Our data support that sacrocolpopexy is a well-tolerated and efficacious procedure, not only in the short-term but also in the long run, that restores not only anatomy but also function. Nevertheless, results should be interpreted in light of the limitations or our study: the relatively small number of patients and a nonrandomized design. On the other hand, a highly standardized surgical technique and close, long-term patient monitoring are important strengths.

In summary, our long-term data further support the role of open abdominal sacrocolpopexy as a treatment choice for patients with POP. The promise—but at the same time the challenge—is the reproduction of its highly satisfactory results by the minimally invasive laparoscopic and robotic techniques. Further research is needed to improve our understanding of the importance of technical details in the efficacy of sacrocolpopexy and the complexity of pathophysiology of urinary and bowel dysfunction in relation to prolapse and its treatment.

Compliance with ethical standards

Conflicts of interest None.

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