ORIGINAL ARTICLE



Anterior bilateral sacrospinous ligament fixation with concomitant anterior native tissue repair: a pilot study

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Abstract

Introduction and Hypothesis Anterior bilateral sacrospinous ligament fixation (ABSSLF) was first described in 2000 but only evaluated in a limited number of studies. However, due to the FDA's ban on transvaginal mesh, interest in this technique has re-emerged. The SSLF procedure is known for its inherent high risk for anterior compartment failure; hence, in our center we started performing a preemptive concomitant anterior repair with the intention to reduce such risk. The aim of this study was to review the feasibility and clinical outcomes of this innovative technique.

Methods We performed a retrospective cohort study of all the women who had an ABSSLF and a concomitant anterior native tissue repair between May 2019 and July 2020 in a tertiary hospital in France. Our primary endpoint was surgical feasibility, while as secondary endpoints we wanted to explore the perioperative morbidities and clinical outcomes associated with this technique.

Results A total of 50 women were operated on in the studied period. The median follow-up time was 10 [8.5] months. It was feasible to perform the combined ABSSLF and concomitant anterior native tissue repair in all cases. The most frequent perioperative complications reported were urinary tract infection (14%) and difficulty in resuming voiding (16%). Anatomical and functional results were improved. The rate of anterior compartment recurrence was 37%.

Conclusions ABSSLF with a concomitant anterior native tissue repair is feasible and relatively safe for treating anterior and apical pelvic prolapse. However, anterior compartment failure rate is still a limitation. Further larger studies with long-term anatomical and functional results comparing this technique to alternative transvaginal surgical approaches are needed.

Keywords Anterior approach \cdot Bilateral sacrospinous ligament fixation (BSSLF) \cdot Native tissue repair \cdot Pelvic organ prolapse \cdot Uterosacral ligament suspension \cdot Vaginal prolapse repair

Abbreviations

ABSSLF Anterior bilateral sacrospinous ligament

fixation

FDA Food and Drug Administration

QoL Quality of life

POP-Q Pelvic Organ Prolapse Quantification SSLF SacroSpinous ligament fixation

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Introduction

Pelvic organ prolapse (POP) occurs in up to 50% of women who have given birth [1]. POP is a pathology that impacts the quality of life of patients and whose prevalence, and hence its management, is increasing because of the aging of the population [2]. Currently, different surgical techniques, using laparoscopic and vaginal approaches, are commonly used to treat concomitant anterior and apical prolapse. However, vaginal surgery remains widespread and has many benefits including the possibility of locoregional anesthesia, lower morbidity, ability to simultaneous manage stress incontinence, the possibility to treat isolated cystoceles or rectoceles, an alternative option to manage recurrences following sacrocolpopexy and a significantly lower mean cost compared to abdominal or laparoscopic sacrocolpopexy [3].



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Vaginal mesh surgery has recently become a widely used technique worldwide. Although associated with improved anatomical results and reduced recurrence rates, there have been concerns about increased morbidities [1]. This led to the eventual FDA ban on the sale and distribution of surgical mesh intended for transvaginal repair of anterior compartment prolapse in 2019 [4]. Since that date, surgeons have had to provide patients with alternative transvaginal procedures that are effective and safe for the treatment of anterior compartment defects. Therefore, surgical techniques utilizing native tissue repairs have come back into the spotlight.

Vaginal sacrospinous ligament fixation (SSLF) is one of the most commonly performed approaches [3]. This technique corrects the prolapse by attaching the cervix or vaginal vault to the sacrospinous ligament with a non-absorbable suture that passes through an opening in the paravaginal or pararectal space depending on whether the approach is anterior or posterior, respectively. It can be performed unilaterally or bilaterally. The procedure risks injuries to the bladder, rectum, pudendal nerve and artery, inferior gluteal artery and sciatic nerve [5]. Initially described by Richter in 1968 [6], SSLF is usually performed unilaterally [7–9] via a posterior approach [6]. However, the choice of the technique and approach influences the anatomical results and recurrence risks. The posterior approach tends to deviate the vaginal apex downwards leaving the anterior compartment more vulnerable to recurrent POP [10, 11]. Therefore, some authors recommend a bilateral approach allowing the vagina to lie in a more horizontal plane and hence lowering the incidence of postoperative cystocele recurrence, proximal vaginal narrowing, de novo dyspareunia and bowel dysfunction [12, 13]. Furthermore, performing a bilateral anterior approach would additionally offer the possibility to perform a concomitant anterior repair in an attempt to reduce anterior compartment recurrences and better respect the natural vaginal axis.

The anterior bilateral sacrospinous ligament fixation (ABSSLF) was first described in 2000 by Cespedes [14]. In his work he reported that the technique was easy to learn and reproduce and that the sacrospinous ligament was easier to visualize and be accessed through an anterior approach with good safety and anatomical results.

Furthermore, Cespedes postulated that bilateral fixation should provide additional support and better long-term outcomes over a single fixation point by increasing the vaginal area above the pelvic floor, thus improving the ability of the vagina to withstand increased intra-abdominal pressure.

Although more recent reports on this technique seem to show good anatomical results with low morbidity [13], there are a limited number of studies that have assessed bilateral fixation using anterior vaginal dissection. Additionally, the high rate of anterior recurrence after SSLF, which seems to occur in more than a third of cases [15], provides

justification for the idea of performing a preemptive concomitant anterior repair [16]. It is for these reasons that we wanted to review the results of a combined ABSSLF and a preemptive concomitant anterior native tissue repair that we started to systematically perform in our unit in 2019. The main aim of this work was to evaluate the surgical feasibility of this approach. As secondary objectives, we wanted to explore the perioperative morbidities, anatomical and functional outcomes associated with this technique.

Materials and methods

This was a retrospective cohort study that included all women who had an ABSSLF with a concomitant anterior native tissue repair between May 2019 and July 2020 in a tertiary urogynecology unit in France. The operative indications for ABSSLF were: POPQ stage ≥ 2 with cystocele and/ or apex prolapse ≥ -1, failure of conservative management and indication for vaginal surgery. All surgical procedures were performed by or under the direct supervision of qualified urogynecologists experienced in this technique. IRB approval was granted for the study by the Delegation for Clinical Research and Innovation of Nimes Hospital on 17 September 2020 (no. 20.09.05).

Surgical technique

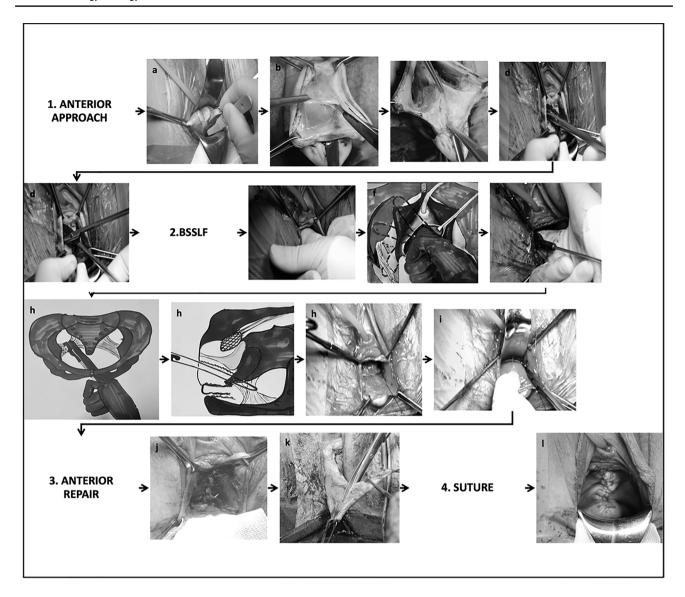
The surgical steps are shown in Fig. 1. Following infiltration of the anterior vaginal wall, a midline anterior colpotomy extended approximately 3 cm below the urethral meatus to about 2 cm before the cervix. The paravesical spaces were then opened bilaterally to expose both sacrospinous ligaments, which were bluntly dissected.

A polypropylene suture was inserted on either side, approximately 2 cm medial to the ischial spines using a Capio Slim device (Capio Slim TM Boston Scientific, Montigny-le-Bretonneux, France). These were anchored with stitches to the anterior part of the cervix (or the uterosacral ligaments in case of a previous or planned concomitant hysterectomy). Some surgeons used a tape attached to the cervix and crossed by propylene yarn (Advantage FitTM Boston Scientific, Montigny-le-Bretonneux, France) to strengthen the cervical stitches. For the anterior repair, the vesicovaginal fibromuscular tissue was placated followed by a vaginal wall repair (colporrhaphy). Any additional concomitant surgeries were performed at the surgeon's discretion and medical indication; these included hysterectomy, rectocele repair and midurethral sling.

Endpoints

The primary endpoint was the feasibility of surgery defined as the ability to perform an ABSSLF with a





1.Anterior approach: a. anterior deep incision, b. cystocele dissection, c. cervix exposition, d. paravesical fossa opening and dissection, **2.BSSLF**: bilateral sacrospinous ligament fixation: e. spine and sacrospinous ligament palpation, f. blunt dissection, g. capio introduction, h. one polypropylene suture (n°0) on both sacrospinous ligament, i. stitch on the cervix, **3. Anterior repair**: j. anterior colporraphy, k. vaginal resection if needed, **4. Suture**: l. vaginal closure

Fig. 1 Surgical technique

concomitant anterior native tissue repair. The secondary endpoints for the study were perioperative morbidities and clinical outcomes. The perioperative complications were reported based on the Clavien-Dindo [17] and ICS-IUGA classifications [18]. Clinical efficacy was assessed between 6 and 12 months after surgery. Anatomical success was objectively assessed by a clinician independent of the study team using the POP-Q score [19], where a

score signifying a POP-Q stage ≥ 2 in the compartment(s) operated on was used as a cut-off for recurrence. The functional results were measured using the validated French versions of the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-IR) [20], the Pelvic Floor Distress Inventory (PFDI-20) questionnaire, the Pelvic Floor Impact Questionnaire (PFIQ-7) [21] and the Patient Global Impression scale Index (PGI-I) [22].



Statistical analysis

Data on clinical characteristics are presented as numbers and frequencies for categorical data and as medians and interquartile ranges [IQR] for continuous data.

Continuous variables were compared using Student's *t*-test or Mann-Whitney test when normal distribution was not verified, while categorical data were compared using chi-square test. The comparison of QoL scores and mean POP-Q scoring between baseline and follow-up was calculated using paired Student's *t*-test or paired Wilcoxon test according to the variable distribution. The threshold of significance was set at 5%. Data analysis were performed using R 2.9.2 (R Development Core Team (2009), R Foundation for Statistical Computing, Vienna, Austria) and XLStat [23].

Results

A total of 50 women were listed for ABSSLF and a concomitant anterior native tissue repair between May 2019 and July 2020. The baseline characteristics of the patients are summarized in Table 1. The median age was 72 years and the median parity was two children. All study participants were menopausal at the time of surgery.

According to the preoperative POP-Q scores, 36 (72%) patients had an apical and/or anterior prolapse stages III–IV and 6 women had previous prolapse surgery.

The main preoperative reported symptoms were urinary and included difficulty in micturition [n=30 (60%)], stress

Table 1 Baseline characteristics of the study population (n=50)

	Median [IQR] or n (%)
Demographics	
Age	72 [8]
BMI	24 [7]
Parity	2 [2]
Postmenopausal	49 (98)
Diabetics	6 (12)
Smoker	3 (6)
Prior surgeries	
Hysterectomy	3 (6)
Prolapse surgery	6 (12)
Urinary incontinence surgery	2 (4)
Sexually activity status	
Sexually active	32 (71)
Not sexually active	13 (29)
Unknown	5

BMI body mass index



urinary incontinence [n=17 (34%)] and an overactive bladder [n=16 (32%)].

The operative parameters and perioperative complications are summarized in Table 2. The procedure was feasible in all cases; of these, 37 (74%) patients had a hysteropexy while 13 (26%) patients had uterosacral ligament fixation to the sacrospinous ligaments due to 10 (20%) and 3 (6%) concomitant and previous hysterectomies, respectively. The median length of hospital stay was 3 [2] days. The rate of postoperative morbidity was 40%. The majority of these were Clavien-Dindo II (34%) and mostly urinary related in the form of urinary tract infection $[n=7 \ (14\%)]$ and postoperative urinary retention $[n=8 \ (16\%)]$ resolved by self-catheterization. There was one serious complication that resulted in left renal colic and acute renal failure secondary to ureteric kinking. However, this resolved with a ureteric catheter without the need for SSLF reoperation.

The median follow-up time was 10 [8.5] months. Compared to baseline, the POP-Q score showed significant improvement in all compartments, and the POP-Q stage was ≤I in 27 women (59%). Three patients (6%) were classified as stage II and one patient (2%) stage III on POP-O because of a de novo rectocele (Table 3). No apical or posterior recurrences were reported. Nevertheless, using our a priori set cut-off, 17 patients (37%) in the study cohort had evidence of an anterior compartment recurrence. However, all these recurrences were limited to stage II (Ba \leq 1). There was improvement in most symptoms postoperatively including difficulty in micturition (p < 0.001), stress urinary incontinence (p = 0.3), overactive bladder (p=0.3) and sexual activity (p=0.1). However, there was a trend to worsening in reported constipation, but this did not reach statistical significance [n=15 (3%) vs. n=13 (2.6%),p = 0.5]. Two patients (4%) underwent a mid-urethral sling procedure for de novo stress urinary incontinence at 2 and 10 months after their prolapse surgery, respectively.

Regarding functional outcomes, the patient global impression scale (PGI) showed good results with 98% of patients reporting considering themselves to be in a "very much better" or "much better" condition compared to before the operation (Table 4). In general, the PFDI-20 and PFIQ-7 questionnaires showed low scores indicating improved QoL. Nonetheless, higher scores tended to be related to the urinary items. The PSIQ-IR showed a weak impact of the condition on sexual function for women who were not sexually active, except for the partner-related items. However, the scores for sexually active women indicated good sexual function (Table 4).

Discussion

This retrospective study confirms that anterior bilateral sacrospinous fixation using the vaginal non-mesh approach combined with an anterior native tissue repair is a feasible

Table 2 Operative parameters and perioperative complications (n=50)

	Median [IQR] n (%)
Anesthesia	
General	34 (68)
Spinal	16 (32)
Local	0
Procedure	
ABSSLF with cystocele repair exclusive	12 (24)
Concomitant surgery	38 (76)
Rectocele repair	31 (62)
Hysterectomy	10 (20)
Midurethral sling for stress incontinence	2 (4)
Surgery time, min	
ABSSLF with cystocele repair exclusive	70 [16]
Concomittent surgery included	126 [20]
ABSSLF feasibility	50 (100)
ABSSLF procedure	
Anatomical suspension	
Hysteropexy	37 (74)
Uterosacral ligament fixation	13 (26)
Suture technique	
PP sutures	28 (60)
PP sutures + tape	19 (40)
ND	3
Early morbidities (<15 days)	
Overall	20 (40)
Clavien-Dindo classification	
I	2 (4)
II	17 (34)
IIIb	1 (2)
IV	0
V	0
IUGA classification	
4BeT1S5	16 (32)
4CeT1S5	1 (2)
6BeT1S4	1 (2)
4BeT2S5	8 (16)
2BT2S1	1 (2)
Category	· /
Ureteral stenosis	1 (2)
Urinary tract infection	7 (14)
Urinary retention	8 (16)
Self-catheterization	14 (28)
Self-catheterization > 10 days	5 (10)
Scar disunion	1 (2)
Hematoma	0
Acute neurological pain	0
New hospitalization	0
1 10 W HOSPITALIZATION	U

Table 2 (continued)

or

	Median [IQR] or n (%)
Late morbidities (15 days to 10 months)	
Overall	4 (8)
IUGA classification	
4BaT3S5	1 (2)
6BbT3S4	1 (2)
6BeT3S5	1 (2)
2AaT4S1	1 (2)
Category	
Chronic pelvic pain	2 (4)
Vaginal tape exposition	2 (4)

IQR interquartile range, ABSSLF anterior bilateral sacrospinous ligament fixation, ND non-data

and relatively safe technique for treating anterior and apical pelvic prolapse.

Both the clinical and functional results were satisfactory, but the efficacy and longer-term recurrence remain to be demonstrated. The technique was feasible in 100% of our study cohort, which is consistent with previous studies showing that intraoperative morbidity is rare with no bowel or bladder accidents or severe bleeding that would have forced the surgeon to interrupt the procedure [13, 16, 24].

The operative durations were variable, and this mainly depended on the additional procedures concomitantly performed. Our average operative duration is comparable to the operative duration reported by Wu et al. [25] of 92 min given that the bilateral approach and rate of additional surgeries performed were similar to ours. However, Shkarupa [24] and Petruzzelli [16] and their associates reported shorter average surgical times of 26 and 41 min, respectively, but they performed a unilateral approach with no concomitant additional procedures undertaken by the former team. According to Plair et al. [9], an anterior sacrospinal hysteropexy has similar short-term efficacy to hysterectomy with an apical repair but with a shorter operative time and a tendency to fewer serious complications. This view supports the current trend to spare the uterus if there is no other reason to remove it.

The most frequent morbidities encountered in our study were urinary tract infection or difficulty in resuming voiding while the most serious was related to ureteric kinking. These findings concur with other reports where Solomon et al. [13] reported difficulty to void with catheter at discharge in about 37% of their patients, and Plair et al. [9] reported one case of ureteral kinking and another of urethral injury. Bastawros and co-workers tested giving nitrofurantoin prophylactically in women with urinary retention after pelvic reconstructive surgery in an attempt to prevent postoperative urinary tract



Table 3 Comparative anatomical results before surgery and at follow-up (median follow-up time = 10 months)

	Before surgery	After surgery	Pre- to postoperative median difference and 95% [CI]	p value
POP Q points (cer	ntimeters)			
Ba				< 0.001
Min	-2.5	-3		
Med [IQR]	2 [3.5]	-2 [1.5]	3.5 [2.7–4.5]	
Max	6	1		
C				< 0.00
Min	-7	-8		
Med [IQR]	1 [3]	-6 [2]	7 [5.5–8]	
Max	8	-2		
Вр				< 0.00
Min	-3	-3		
Med [IQR]	-1 [-1.75]	-3 [0.5]	1.5 [0.75–2.25]	
Max	1	2		
POP Q stage (n (%	(é))			
Global				
0	0	12 (26)	-	< 0.00
I	1 (2)	15 (33)	-	< 0.00
II	13 (26)	18 (39)	-	0.17
III	27 (54)	1 (2)	-	< 0.00
IV	9 (18)	0	-	0.00
ND	0	4	-	-
Anterior domain				
0	0	14 (30)	-	< 0.00
I	2 (4)	15 (33)	-	< 0.00
II	18 (36)	17 (37)	-	0.9
III	26 (52)	0	-	< 0.00
IV	4 (8)	0	-	0.05
ND	0	4	-	-
Apical domain				
0	5 (10)	43 (94)	-	< 0.00
I	5 (10)	3 (6)	-	0.5
II	15 (30)	0	-	< 0.00
III	19 (38)	0	-	< 0.00
IV	6 (12)	0	-	0.002
ND	0	4	-	-
Posterior domain				
0	1 (2)	31 (68)	-	< 0.00
Ī	25 (53)	12 (26)	-	0.008
II	20 (43)	2 (4)	-	< 0.00
III	1 (2)	1 (2)	-	0.99
IV	0	0	-	-
ND	3	4	_	

Med median, POP-Q Pelvic Organ Prolapse Quantification, ND non-data

infections, but there was no reduction in the infection rate compared to the placebo group [26]. Regarding the risk of urinary retention, Chapman et al. demonstrated in a randomized placebo-controlled trial that the use of tamsulosin

was associated with reduced rates of postoperative urinary retention after female pelvic reconstructive surgery [27].

Based on the POP-Q score, there was a significant improvement in the anatomical outcomes in line with those reported by Petruzzelli who treated prolapse using a



Table 4 Functional results at follow-up

	
PGI-I (n=40)	n (%)
Better (1–2)	39 (98)
Unchanged (3–4–5)	1 (2)
Worst (6–7)	0
PFDI-20 $(n=42)$	Median [IQR]
Summary score	31 [62]
POPDI-6	4 [21]
CRADI-8	9 [19]
UDI-6	8 [25]
PFIQ-7 (<i>n</i> =41)	Median [IQR]
Summary score	0 [24]
UIQ-7	0 [10]
CRAIQ-7	0 [6]
POPIQ-7	0 [0]
PISQ-IR (n=37)	
Sexual activity status	n (%)
NSA	23 (46)
SA	14 (28)
Scale scores: NSA ^a	$Mean \pm SD$
NSA-PR	90 ± 27
NSA-CS	15 ± 36
NSA-GQA	30 ± 27
NSA-CI	8 ± 21
Scale scores: SA ^b	$Mean \pm SD$
SA-AO	55 ± 16
SA-PR	73 ± 20
SA-CS	86 ± 16
SA-GQ	57 ± 30
SA-CI	93 ± 10
SA-D	39 ± 14

IQR interquartile range, SD standard deviation

PGI-I Patient Global Impression scale Index

PFDI-20 Pelvic Floor Distress Inventory

It included three domains with lower scores associated with better quality of life (min 0—max 300)

POPDI-6 Pelvic Organ Prolapse Distress Inventory (min 0—max 100)

CRADI-8 Colorectal-Anal Distress Inventory (min 0-max 100)

UDI-6 Urinary Distress Inventory (min 0-max 100)

PFIO-7 Pelvic Floor Impact Questionnaire

It included three domains with lower scores associated with better quality of life (min 0—max 300)

UIQ-7 Urinary Impact Questionnaire

CRAIQ-7 Colorectal-Anal Impact Questionnaire

POPIQ-7 Pelvic Organ Prolapse Impact Questionnaire

PISQ-IR Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire

NSA not sexually active

SA sexually active

^aHigher scores indicate greater impact of condition on sexual function (high score negative) (min 0-max 100)

Table 4 (continued)

bHigher scores indicate better sexual function (high scores positive) (min 0-max 100)

NSA-PR not sexually active: partner related NSA-CS not sexually active: condition specific

NSA-GQA not sexually active: global quality rating NSA-CI not sexually active: condition impact

SA-AO sexually active: arousal, orgasm
SA-PR sexually active: partner related
SA-CS sexually active: condition specific

SA-GQ sexually active: global quality SA-CI sexually active: condition impact

SA-D sexually active: desire

combined approach of sacrospinous hysteropexy and cystopexy through a single anterior incision [16]. Similarly, our study demonstrated improvement in several functional outcomes, which is consistent with the findings reported by Yalcin et al. [28]. Nevertheless, we observed a notable rate of persistent constipation after surgery (30% versus 26%, p=0.5). Women should be made aware of the risk of persistence of this problem and that it might require long-term medical management.

Despite performing a routine concomitant anterior repair, the anterior compartment recurrence rate remained high, reaching 37%. However, it is important to stress that all these recurrences were limited to stage II (Ba \leq 1) and that our results are not an outlier compared to those reported in the literature. Although our recurrence rate was high, it is lower than that reported by other studies that did not perform a prophylactic cystocoele like Shkarupa et al. [24] and Jelovsek et al. [29] who reported recurrence rates of 45% at 12 months and 70% at 5 years, respectively. Shkarupa et al. performed an anterior bilateral approach while Jelovsek et al. performed unilateral or bilateral SSLF, but the approaches, anterior or posterior, were not specified. A recent metaanalysis [15] including two randomized controlled trials and four cohort studies on sacrospinous hysteropexy via a posterior approach calculated the failure rate in the anterior compartment of 35%. Moreover, our recurrence rate was better than the 90% recurrence rate at 1 year (50% stage I, 40% stage II) reported by De Castro et al. who also hoped to obtain a reduction in previous recurrences by undertaking a prophylactic cystocele cure. However, they used a posterior approach for their unilateral SSFL procedures [30]. In contrast, Solomon et al. [13] reported no recurrence rates but they only followed up their patients at 6 months. Furthermore, our study participants had preoperative prolapses of stages II to IV compared to the majority of patients in the study by Salomon et al. being stage II. Indeed, with native tissue apical vaginal surgery, the degree of preoperative



prolapse is an important predictor of anatomical outcomes [31]. Interestingly, in a relatively large study of 453 patients who had unilateral SSLF, with or without a concomitant cystocele cure, and an average 5-year follow-up, anterior compartment prolapse was the most frequently encountered type of recurrence at a rate of about 12.6%, and a statistical regression analysis showed that anterior colporrhaphy was not a significant risk factor contributing to this recurrence [25].

The anterior and bilateral approach is attractive because it allows for a concomitant anterior repair and is suggested to reduce the risk of anterior compartment recurrence rate by more uniform distribution of the tensile forces and thus respecting the anatomical axis. Hence, some authors suggest that, pending further randomized clinical trials, an anterior repair should be considered for women with higher-stage prolapse undergoing an SSLF [31]. Nevertheless, we have not shown this benefit in our preliminary study.

Apart from the additional data this study adds to the literature regarding ABSSLF and a concomitant native anterior repair, our study has the main strength that experienced urogynecological surgeons carried out all the procedures. Furthermore, we assessed a comprehensive set of outcomes that included both clinical and patient-reported outcomes. Our anatomical outcomes were assessed independently, and all our patient-reported outcomes were evaluated using validated measures. However, we appreciate that the retrospective nature and short-term follow-up are limitations to our work. We also recognize that our sample size is relatively small; this was mainly secondary to the recurrent COVID-19 restrictions imposed on elective procedures during the studied period. Moreover, there is a degree of heterogeneity in the surgical techniques used among our surgeons, at least initially, where some used a cervical tape. At present, we only use sutures because of the potential risk and the lack of evidence demonstrating the superiority of the tape.

Conclusion

Anterior bilateral sacrospinous ligament fixation using the vaginal non-mesh approach combined with a routine anterior native tissue repair is a feasible and relatively safe technique for treating anterior and apical pelvic prolapse with satisfactory anatomical and functional results at the short term. However, anterior compartment failure rates are still a limitation. Assessing the long-term anatomical and functional outcomes of this technique compared to other available surgical options is needed before drawing final conclusions.

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Author contributions C. Delacroix: Data collection, data management and manuscript writing.

- L. Allegre: Protocol development, data analysis and manuscript writing.
 - K. Chatziioannidou: Data collection and data analysis.
 - A. Gérard: Data management, data analysis.
 - B. Fatton: Data analysis, data interpretation.
- R. De Tayrac: Principal investigator during this work, project development, data analysis, data interpretation and manuscript writing.

All authors reviewed and/or edited the manuscript prior to submission.

Declarations

Conflict of interest Prof. De Tayrac and Dr. Fatton are consultants for Boston Scientific; remaining authors claim no conflict of interest.

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