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# Mid-term outcomes of moderate-severe cystocele repairing with autologous fascia lata harvested through a small incision

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## Abstract

**Introduction and hypothesis** To investigate the mid-term outcomes of transvaginal repair for moderate-severe cystocele using autologous fascia lata harvested through a single small incision.

**Methods** Between February and October 2022, 35 patients with moderate to severe cystocele undergoing transvaginal repair with autologous fascia lata were included. Patient demographics and perioperative data were collected, with follow-ups through outpatient visits or phone calls. Patients were evaluated by subjective perception of vaginal bulging, physical examination, Pelvic Floor Distress Inventory (PFDI-20) Questionnaire, patient satisfaction, Patient Global Impression of Improvement (PGI-I) scores, regret rate, willingness to recommend, complications, and harvesting site issue.

**Results** The patient's mean age was  $60.44 \pm 6.01$  years. Fascia lata harvesting took  $32.92 \pm 19.72$  min, reconstruction surgery lasted  $141.21 \pm 37.89$  min. Follow-up duration was  $15.94 \pm 2.46$  months. 5.7% (2/35) of the patients reported a non-interfering vaginal bulge not requiring treatment. Objective recurrence rate was 4.26% (1/24, Aa or Ba>0) PFDI-20 was significantly improved ( $P < 0.0001$ ). All 35 patients (100%) were highly satisfied, with PGI-I score very much improved or improved. No patient regretted. 97.14% (34/35) would recommend the procedure. One patient developed poor wound healing at the vaginal apex. One patient developed thromboembolic event. Harvest site: 2.86% (1/35) developed a non-bothersome thigh bulge, 17.14% (6/35) noted an impact on wound appearance, and 8.57% (3/35) reported mild paresthesia.

**Conclusion** Autologous fascia lata for cystocele treatment shows promising mid-term outcomes, safely and effectively enhancing QoL with high satisfaction. Despite concerns about leg scarring, no patient regretted and would recommend the procedure. Long-term outcomes require larger follow-up studies.

## Brief summary

Autologous fascia lata harvested in small incision for cystocele treatment is safe and effective, enhancing QoL with high satisfaction.

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**Keywords** Autologous fascia lata, Pelvic organ prolapse, Cystocele, Anterior vaginal wall repair, Pelvic floor reconstruction

## Introduction

Anterior vaginal wall prolapse is the most prevalent type of pelvic organ prolapse (POP) in women and exhibits the highest rate of postoperative recurrence. Traditional repair surgeries that involve folding and suturing the weak fascial tissue tend to have a high recurrence rate [1]. Augmenting the repair with alternative materials proves effective in reducing recurrence. Clinically used alternative materials include meshes and biological grafts. However, the complications associated with mesh, such as postoperative erosion, exposure, and pain, may inflict greater harm on patients [2–4]. In 2019, the U.S. Food and Drug Administration (FDA) banned transvaginal mesh (TVM). Although TVM has not been banned in China, its use is limited by the Female Pelvic Floor Study Group under the Chinese Medical Association's Obstetrics and Gynecology Branch [5]. However, biological grafts, may not provide adequate repair due to rapid degradation of the biomaterials leading to insufficient local biomechanical performance after degradation [4].

Autologous fascial tissue elicits no foreign body reaction and can exhibit robust biomechanical properties. For instance, it can be a viable alternative for repairing tendons and ligaments in sports-related injuries [6]. In the field of urogynecology, autologous fascia, such as fascia lata and rectus fascia, has been used primarily for mid-urethral sling procedures, with some utilization in vaginal apex suspensions. However, the use of autologous fascia declined following the emergence of synthetic materials [7–9]. In recent years, due to the limitations of various alternative materials, particularly mesh, there has been a renewed interest among urogynecologists in utilizing autologous fascia. Existing reports on harvesting autologous fascia typically involve multiple or lengthier skin incisions, for vaginal apex suspension or cross-placed fascial strips in the anterior wall [10–12].

In this study, we harvested two strips of autologous fascia lata through a single small incision. After suturing the high sacrospinous ligament and dissecting the vesicovaginal space, the first fascial strip was transversely fixed at the level of the bladder neck through bilateral obturator punctures. The second fascial strip was folded in half, attached to the first strip in the middle, and placed over the vesicovaginal space, with the proximal end sutured to the vaginal stump and suspended to the high uterosacral ligament. This method simultaneously repairs both levels I and II of the anterior vaginal wall. This study aims to evaluate the safety and efficacy of this technique through mid-term postoperative outcomes.

## Materials and methods

### Study subjects

Thirty-five patients underwent gynecological surgery at Peking University Third Hospital between February 2022 and October 2022. All patients provided written informed consent before participating in the study. This study was performed in line with the principles of the Declaration of Helsinki. The study was approved by the Research Ethics Committee of Peking University Third Hospital (NO: IRB00006761-M2022853).

### Inclusion criteria

- (1) Patients diagnosed with symptomatic stage III-IV (POP-Q staging) anterior vaginal wall prolapse, who have chosen to undergo transvaginal anterior wall repair with autologous fascia lata after reviewing educational materials and engaging in thorough patient-doctor communication.
- (2) Concurrent uterine prolapse or posterior vaginal wall prolapse may also be present.

### Exclusion criteria

- (1) History of previous pelvic organ prolapse surgery.
- (2) Diagnosis of malignant tumors during or after surgery.

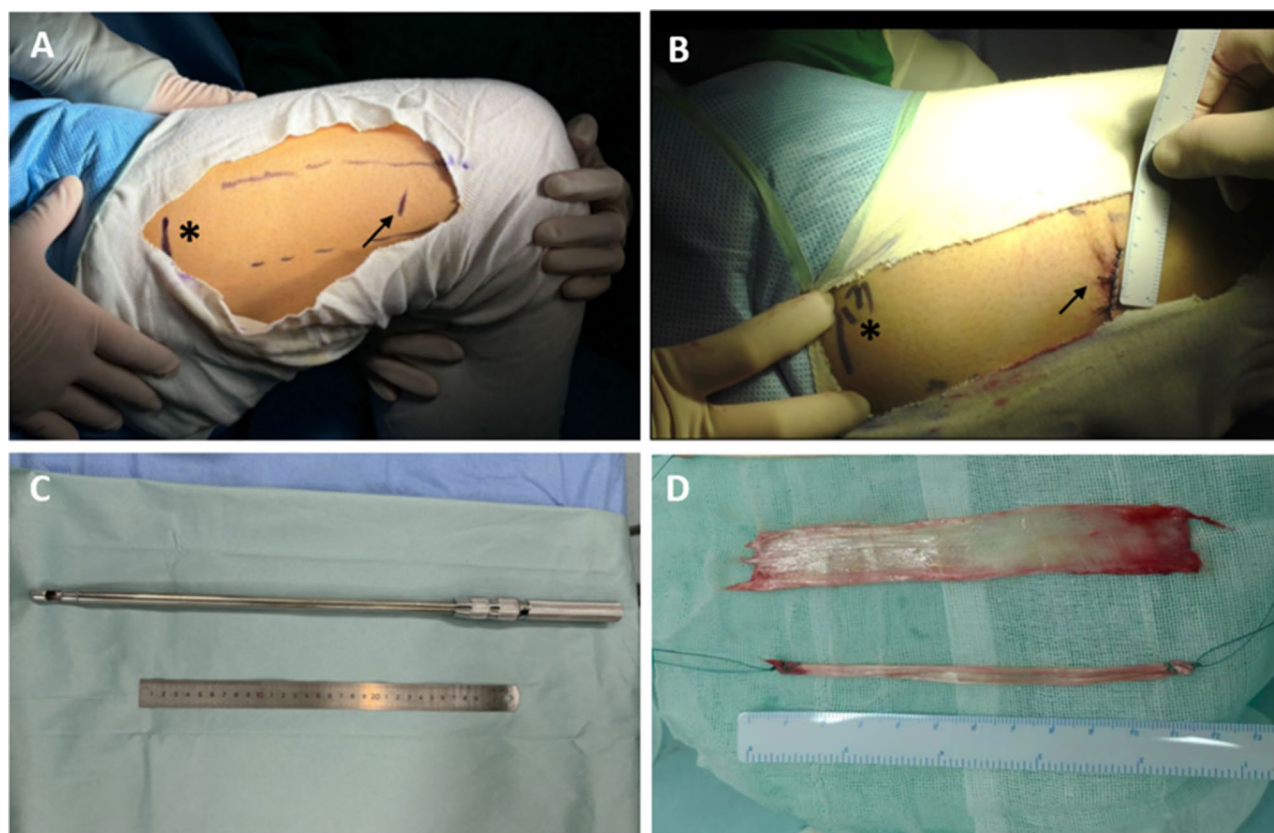
### Preoperative preparation

All patients were evaluated by a urogynecologist, including POP-Q staging and PFDI-20 questionnaire [13]. In addition to routine preoperative examinations, lower limb venous ultrasound was also required. Three days prior to surgery, patients were instructed to take potassium permanganate sitz baths, and their vaginas were irrigated twice daily with 5% chlorhexidine solution two days before surgery.

### Surgical procedure

#### 1. Fascia Lata Harvest

After induction of general anesthesia, the patient is positioned in a supine posture. If there is no history of prior surgery on the right thigh, the right thigh is preferred. After routine disinfection and draping procedures, the area for harvesting fascia lata is delineated (Fig. 1A). The upper boundary is marked along the line connecting the anterior superior iliac spine to the lateral tibial condyle, and the lower boundary along the line connecting the



**Fig. 1** **A:** the marking lines for harvesting the fascia lata, (→) indicating the incision site and (\*) marking the endpoint of the tendon stripper; **B:** the incision approximately 3 cm in length; **C:** the tendon stripper; **D:** two fascia strips, measuring 12–14 cm in length, and 1–1.5 cm and 2–2.5 cm in width respectively

greater trochanter to the lateral tibial condyle. The incision is marked 10 cm above the lateral tibial condyle, perpendicular to the longitudinal axis of the thigh, and a skin incision approximately 3 cm in length is made (Fig. 1B). A stripper (Fig. 1C) was used to harvest the fascia measuring 12–14 cm in length, and 1–1.5 cm and 2–2.5 cm in width respectively (Fig. 1D). The ends of the first thin fascia strip are sutured with 2–0 non-absorbable sutures (Ethibond®, Ethicon, USA) for obturator puncture. The wound is closed routinely, and the harvest site is compressed with an elastic bandage.

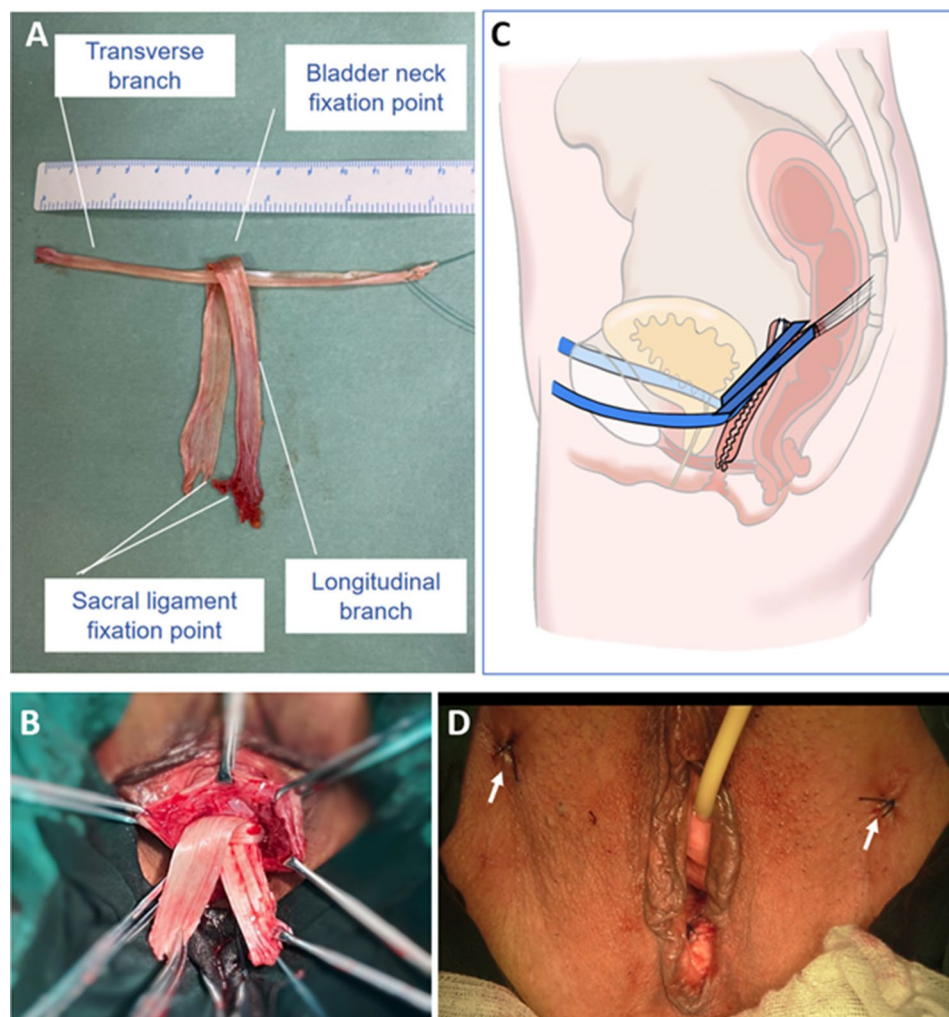
## 2. Fascia Lata Augmentation of the Anterior Vaginal Wall

After performing a vaginal hysterectomy and high uterosacral ligament suspension, the suspension sutures on both sides of the uterosacral ligament are preserved. The vesicovaginal space is opened, with dissection extending distally to 3 cm below the bladder neck and laterally to the posterior of the pubic rami. A purse-string suture using 2–0 absorbable sutures is applied to the fascia overlying the prolapsed bladder. Puncture points are marked at the level of the urethral orifice intersect with

the genital fold on both sides. The first thin fascia strip is guided through the obturator puncture tool from outside to inside. The second fascia strip is placed centrally over the first strip, folded in half to form a sheet, and laid over the vesicovaginal space (Fig. 2A and D). After fixation of the fascia strips, the proximal end is sutured to the vaginal stump, then suspended together to the high uterosacral ligament.

## Postoperative management

On the first day after surgery, patients are encouraged to start moving and perform ankle pump exercises. For high-risk patients, heparin is given 24 hours postoperatively to prevent thrombosis. On the second or third day after surgery, the iodine gauze strips in the vagina are removed, the urinary catheter is removed, and the residual urine volume is measured. Routine postoperative care includes the administration of antibiotics to prevent infection and pain management. The elastic bandages on the lower limbs are taken off one week after surgery. Sutures on the vulva and thigh are removed two weeks after surgery.



**Fig. 2** **A** and **B**: placement of the fascia strips. The first thin fascia strip is placed horizontally at the level of the bladder neck and is fixed on both sides through obturator punctures. The second fascia strip is folded and suspended over the horizontal fascia strip, with the proximal end sutured to the vaginal stump and both suspended together to the high uterosacral ligament. **C**: schematic diagram of the suturing of the two fascia strips; **D**: obturator puncture fixation point (→)

## Statistical data and follow-up

### 1. General Information

Age, Body Mass Index (BMI), parity, menopausal status, history of hysterectomy, medical comorbidities, proportion of high-risk factors for pelvic organ prolapse (e.g., delivering a large baby, chronic constipation, or coughing, heavy physical labor, more than two deliveries), the duration of prolapse, preoperative POP-Q staging and PFDI-20 questionnaire results.

### 2. Perioperative Data

Duration of fascia harvesting surgery and pelvic floor reconstruction surgery, blood loss, blood transfusion, intraoperative complications, 24-hours post-surgery

thigh pain, urinary catheter retention days, urinary retention, and postoperative hospital stay.

### 3. Follow-up

Outpatient follow-up at 2 months post-surgery, with additional follow-ups at 6 months, 1 year, and annually thereafter via outpatient visits or telephone.

Follow-up Content Includes:

1. Subjective Recurrence Symptoms: Whether the patient experiences a bulge at the vaginal opening.
2. POP-Q Staging for Outpatient Follow-up Patients, objective recurrence: Aa>0 or Ba>0.
3. PFDI-20 Questionnaire.
4. Patient Satisfaction: Very satisfied, Satisfied, Unsure, Dissatisfied, Very dissatisfied.



**Table 1** General Information ( $n = 35$ )

Parameter	Mean $\pm$ SD/Value(%)
Age (years)	60.44 $\pm$ 6.01
BMI (kg/m <sup>2</sup> )	25.64 $\pm$ 3.82
Parity	1.77 $\pm$ 0.79
Menopause	33/35 (94.28%)
Menopause time (years)	10.18 $\pm$ 6.88
History of hysterectomy	3/35 (8.57%)
Complication	
History of hypertension	15/35(42.85%)
Presence of diabetes	8/35(22.85%)
History of heart disease	3/35(8.57%)
High risk factors	
History of macrosomia delivery	7/35(20%)
Chronic constipation	2/35(5.71%)
Chronic cough	2/35(5.71%)
Heavy physical labor	27/35(77.14%)
Multiple labor(>2)	6/35(17.14%)
Prolapse symptoms duration(months)	36.24 $\pm$ 33.39

BMI: body mass index

5. Patient PGI-I Score [14]: ①. very much improved, ②. improved, ③. little improved, ④. no change, ⑤. slightly worse, ⑥. worse, ⑦. very much worse.
6. Whether the Patient Regrets Choosing This Surgery.
7. Willingness to Recommend This Surgery to Others.
8. Postoperative Complications: The classification of complications involving augmented grafts using the Native Tissue Surgery Complications (CTS) classification [15], and the Clavien-Dindo classification [16].
9. Harvesting site: Whether it affects appearance, whether it is paresthesia, and whether there is any thigh bulge.
10. Postoperative Sexual Activity: Whether the patient has engaged in sexual activity postoperatively, and whether there are any difficulties or discomfort during sexual activity.

### Statistical methods

Statistical analysis was performed using SPSS Version 26.0 (IBM, Armonk, NY, USA). Continuous variables were summarized using means and medians. The analysis of continuous variables was conducted using the t-test. Categorical variables were summarized using frequencies and percentages. The analysis of categorical variables was conducted using the chi-square test. A  $P < 0.05$  was considered statistically significant.

## Results

### 1. General Information

**Table 2** Perioperative Information( $n = 35$ )

Parameter	Mean $\pm$ SD/Value(%)
Total Operative Time (min)	179.61 $\pm$ 41.72
Harvest fascia lata Time (min)	32.92 $\pm$ 19.72
Pelvic floor reconstruction surgery Time (min)	141.21 $\pm$ 37.89
Peroperative bleeding (ml)	75.55 $\pm$ 50.67
Pain in lower limbs within 24 h after surgery	5/35 (14.28%)
Postoperative catheter indwelling time (day)	2.14 $\pm$ 0.60
Postoperative hospital stay (day)	3.40 $\pm$ 1.31

The mean age of the 35 patients was 60.44  $\pm$  6.01 years, There was 2.8% (1/35) under the age of 50, 42.9% (15/35) in the age range of 50–60, and 54.3% (19/35) over the age of 60. with a mean duration of prolapse of 36.24  $\pm$  33.39 months. The general patient information is shown in Table 1.

### 2. Perioperative Data

The average duration of the fascia harvesting procedure was 32.92  $\pm$  19.72 min, and the duration of the reconstruction surgery was 141.21  $\pm$  37.89 min. Except for 3 patients who had previously undergone a hysterectomy, all other patients underwent vaginal hysterectomy simultaneously. All patients underwent transvaginal high uterosacral ligament suspension. Mild pain at the harvesting site was reported in 14.28% (5/35) of patients 24 hours after the operation, but it did not affect their mobility. There were no intraoperative complications, no cases of blood transfusion, and no postoperative urinary retention. Perioperative information is provided in Table 2. The total cost for the patient was 19,522.28  $\pm$  3,801.57 CNY, which included a surgical fee of 6,872.98  $\pm$  1,068.18 CNY and an anesthesia fee of 1,352.87  $\pm$  317.55 CNY.

### 3. Follow-up Results

The average follow-up duration for the 35 patients was 15.94  $\pm$  2.46 months, with all patients attending an outpatient follow-up at 2 months post-surgery. Among them, 68.6% (24/35) of patients had their last follow-up as an outpatient visit, with an average follow-up duration of 15.91  $\pm$  2.70 months, while the remaining follow-ups were conducted via telephone. Among the 35 follow-up patients, 5.7% (2/35) reported feeling a bulge at the vaginal opening, which did not affect their daily life. Both of these patients fall within the age range of 50 to 60. The objective recurrence rate was 4.26% (1/24), and there were no cases requiring reoperation. The POP-Q score for patients who had outpatient follow-up is presented in Table 3.

Preoperative and postoperative PFDI-20 Scores for 35 Patients were compared, 72.84  $\pm$  38.05 vs. 9.48  $\pm$  11.2,  $P < 0.0001$ . Patient Satisfaction: 100% (35/35) of patients

**Table 3** Preoperative and postoperative POP-Q score( $n=24$ )

Parameter	Preoperative	Postoperative	P value
Aa	$2.50 \pm 1.24$	$-2.50 \pm 1.15$	$P < 0.0001$
Ba	$4.20 \pm 2.22$	$-2.58 \pm 1.10$	$P < 0.0001$
C	$1.93 \pm 3.21$	$-5.97 \pm 2.40$	$P < 0.0001$
Ap	$-1.34 \pm 1.89$	$-2.80 \pm 1.19$	$P < 0.0001$
Bp	$0.47 \pm 2.69$	$-2.69 \pm 0.95$	$P < 0.0001$
Gh	$5.51 \pm 0.70$	$4.2 \pm 0.40$	$P < 0.0001$
Pb	$2.04 \pm 0.70$	$3.30 \pm 0.52$	$P < 0.0001$
TVL	$6.79 \pm 0.55$	$6.71 \pm 0.62$	$P = 0.44$

reported being very satisfied. PGI-I Scores: 74.29% (26/35) of patients reported very much improved, and 25.71% (9/35) reported improved. None of the patients regretted choosing the surgery. 97.14% (34/35) of patients were willing to recommend this surgery to others.

**Postoperative Complications:** One patient underwent a debridement surgery two months after the operation due to poor healing of the vaginal apex wound. This was classified as 1BT2S1 and Clavien-Dindo IIb. One patient developed an intermuscular venous thrombosis in the right lower limb, which resolved after one month of anti-coagulant therapy.

**Harvesting site:** One patient reported a non-bothersome thigh bulge. 17.14% (6/35) noted an impact on wound appearance and 8.57% (3/35) reported mild paresthesia.

**Sexual Activity:** 57.14% (20/35) of patients were sexually active before surgery and resumed normal sexual activity two months postoperatively. 11.43% (4/35) of patients who were sexually active before surgery, delayed resuming sexual activity until one year postoperatively due to concerns about wound healing. None of these patients reported difficulties with sexual intercourse. 25.71% (9/35) of patients were not sexually active before or after surgery due to social factors. Two patients did not answer this question.

## Discussion

The use of transvaginal synthetic mesh in pelvic floor reconstruction surgeries has been restricted due to complications such as exposure, erosion, and pain. These complications can persist and affect patients for many years after surgery. Zhang's study showed a mesh exposure rate of 28.4% after an 11-year follow-up [17]. Similarly, Yang's long-term follow-up on transvaginal mesh (TVM) revealed that the average time to mesh exposure was 3 years, with some cases occurring up to 11 years [18]. As a result, the International Urogynecological Consultation (IUC) recommends lifelong outpatient follow-up for patients undergoing mesh surgeries [19]. In China, the use of mesh has been restricted to patients over 60 years old, limiting the surgical options for younger patients with severe anterior vaginal wall prolapse [20].

In our study, 45.7% of the patients were under 60 years old. Therefore, to reduce the recurrence rate, autologous fascia may be an option. In recent years, there has been an increase in the use of autologous fascial tissue. We have reported a surgical technique that involves transvaginal augmentation with autologous fascia lata for treating moderate to severe anterior vaginal wall prolapse.

The fascia lata and rectus fascia are the two most commonly used autologous fascia types reported in the literature. The success rates of these two types of fascia in vaginal apex suspension surgeries are similar [21]. Complications at the harvest sites of these two types of fascia vary. Some studies indicate that the incidence of abdominal wound complications, poor wound healing, and hematoma is significantly higher in the rectus fascia group compared to the fascia lata group [22]. While others indicate that complications at the fascia lata harvest site are more common but generally milder [21].

We chose fascia lata as the substitute material for repairing anterior vaginal wall because it allows for the harvesting of a larger area, thus avoiding complications like abdominal wall hernias that can occur from excessive rectus fascia. A systematic review comparing the two types of fascia also suggests that fascia lata can be harvested at a greater width [21]. The total width we harvested was approximately 4 cm, with a length of about 12–14 cm, which is consistent with literature reports [10, 23–25]. However, we used a single small incision, about 3 cm in length to minimize trauma. The average harvesting time was  $32.92 \pm 19.72$  min, and only 14.28% of patients experienced mild pain within 24 h after surgery, which did not affect their mobility.

A systematic review of 13 studies involving 550 patients examined the use of autologous fascia for vaginal apex suspension. The results showed that the success rate for fascia lata was approximately 83–100% (with follow-up periods ranging from 12 to 52 months), approximately 87–100% for rectus fascia (with follow-up periods ranging from 12 to 98 months) [21]. Ralph et al. used autologous fascia lata in the treatment of severe or recurrent anterior vaginal wall prolapse, with an average follow-up period of 9 months and a recurrence rate of 6.25% (2/32) [9]. Our study indicates that during mid-term follow-up, only 5.7% of patients reported feeling a bulge at the vaginal opening, and objective recurrence rate was 4.26%, which did not affect their daily life, and none requested further treatment. Patient satisfaction rate was 100%, and 74.29% of patients reported very much improved and 25.71% reported improved according to the PGI-I scores.

These complications at harvesting site include paresthesia, swelling, thigh bulge, hematoma, deep vein thrombosis, and wound healing [21]. The incidence of paresthesia at the autologous fascia harvest site ranges from 10.6–35% [10, 11, 23], swelling occurs in 10.5% of

cases [11], thigh pain is reported in 4% of cases [25], and thigh bulge occurs at a rate of 8.8–15% [10, 23]. Hematoma incidence ranges from 2.9–12% [10, 11, 23], with a 5.3% probability of requiring transfusion due to hematoma [11], and the rate of deep vein thrombosis formation is 5.3% [11]. In our study, 2.85% (1/35) of patients experienced a non-bothersome thigh bulge. Additionally, 8.57% (3/35) of patients reported paresthesia. One patient (2.85%) developed an intermuscular venous thrombosis, which resolved after one month of anticoagulant therapy. Our findings are consistent with the literature, and we demonstrated that it is safe and feasible to harvest a large fascia lata using a more minimally invasive approach. Although the incision for fascia lata harvest was only 3 cm, 17.14% of patients felt it affected their appearance. However, none of the patients regretted choosing this surgical method, and 97.14% were willing to recommend it to others. Harvesting site scars are inevitable when using autologous fascia, we look forward to having more minimally invasive methods in the future.

Compared to synthetic and allograft materials, autologous grafts have fewer complications and higher healing and re-epithelialization capabilities [26]. However, there is still a risk of poor wound healing. Powell et al. reported that 10% of patients who underwent pelvic floor reconstruction with fascia lata experienced poor wound healing at the pelvic site [12]. This percentage includes both autologous fascia and donor fascia, but wound healing improved with debridement and vaginal estrogen treatment without the need to remove the fascia lata. In our study, 2.85% (1/35) of patients experienced poor wound healing at the vaginal apex. A debridement surgery was performed two months postoperatively, resulting in eventually successful healing without removing the transplanted fascia lata.

The long-term vitality of autologous fascia after transplantation is a critical concern. The American Academy of Orthopaedic Surgeons guidelines for the treatment of anterior cruciate ligament injuries (ACL) recommend considering the use of autologous grafts, such as hamstring tendon grafts, particularly for young and/or athletic patients [27]. Regarding the long-term outcomes of autologous fascia at the transplantation site, in a case study by Durante J et al., autologous rectus fascia used in urinary incontinence surgery remained identifiable and showed slight adhesions to surrounding tissue even 16 years later during reoperation for bladder cancer. Histopathology revealed fibrous hyperplasia, capillary formation, and an inflammatory infiltrate predominantly composed of lymphocytes and plasma cells [28]. Ahlen et al. found that autologous semitendinosus tendon used to reconstruct the cruciate ligament in the knee showed a similar histological appearance to the contralateral knee after an average follow-up period of

8.4 years post-surgery suggesting potential regeneration and normalization of autologous fascia after implantation [6]. FitzGerald et al.'s study showed that autologous rectus fascia used as a urethral sling exhibited fibrous hyperplasia, vascular regeneration, and tissue remodeling four years post-surgery without signs of inflammation or tissue degeneration [29]. However, there are also reports indicating moderate degeneration of autologous fascia 2–65 months after implantation, with no fibrous encapsulation or infection, and only moderate fibroblast infiltration and limited vascular regeneration [30]. Therefore, the long-term outcomes of autologous fascia require further investigation.

The cost for autologous fascia reconstruction surgery was  $19,522.28 \pm 3,801.57$  CNY, compared to the 5,000–15,000 CNY charged for synthetic mesh procedures. Economically, using autologous fascia reduces the financial burden on patients.

The limitation of this study is that, this is a single-center retrospective study, which may induce recall bias in patients' reports of harvesting site pain 24 h post-surgery and sexual activity condition, and the results need to be further confirmed by a single-center or multicenter prospective study. This study involved only 35 patients, and only 24 POP-Q score evaluations were obtained due to their residence in other cities.

## Conclusion

Until an ideal pelvic floor repair material is developed, the mid-term outcomes of using autologous fascia lata for the treatment of moderate to severe anterior vaginal wall prolapse suggest that this technique is safe. It effectively improves patients' quality of life and has a high satisfaction rate. Although a few patients expressed concerns about the harvesting site appearance, none regretted choosing this surgery and were willing to recommend it to others. Further study with a larger number of cases and extended follow-up is needed to investigate the long-term outcomes of this surgery.

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Not applicable.

## Author contributions

BoYu: data collection and management, data analysis, manuscript writing; Junfang Yang: data collection, surgeon; Qingyang Nie: data collection and management; Kun Zhang: data collection, surgeon; Jin-song Han: surgeon, manuscript editing; Yiting Wang: surgeon, manuscript editing, project development. All authors reviewed the manuscript.

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## Data availability

The data that support the findings of this study are available from the corresponding author upon reasonable request.

## Declarations

### Ethics approval and consent to participate

This study was performed in line with the principles of the Declaration of Helsinki. The study was approved by the Research Ethics Committee of Peking University Third Hospital (NO: IRB00006761-M2022853). Informed consent was obtained from all individual participants included in the study.

### Consent for publication

Not applicable.

### Competing interests

The authors declare no competing interests.

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