Original Article

Porcine Small Intestinal Submucosa Mesh for Treatment of Pelvic Organ Prolapsed

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Abstract

Background: Pelvic organ prolapse (POP) is a major health concern that affects women. Surgeons have increasingly used prosthetic meshes to correct POP. However, the most common used is synthetic mesh, and absorbable mesh is less reported. This research aimed to evaluate the clinical effectiveness of porcine small intestinal submucosa (SIS).
Methods: Consecutive forty POP patients who met the inclusion criteria underwent pelvic reconstruction surgery with SIS between March 2012 and December 2013. The patients' clinical characteristics were recorded preoperatively. Surgical outcomes, measured by objective and subjective success rates, were investigated. We evaluated the quality of life (QOL) using the Pelvic Floor Distress Inventory-20 (PFDI-20) and the Pelvic Floor Impact Questionnaire-7 (PFIQ-7). Sexual QOL was assessed by the Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire-12 (PISQ-12).
Results: At postoperative 12 months, the subjective recurrence rate (7.5%) was much lower than the objective recurrence rate (40.0%). Postoperatively, no erosion was identified. One underwent a graft release procedure because of urinary retention, and one had anus sphincter reconstruction surgery due to defecation urgency. Another experienced posterior vaginal wall infection where the mesh was implanted, accompanied by severe vaginal pain. Estrogen cream relieved the pain. One patient with recurrence underwent a secondary surgery with Bard Mesh because of stage 3 anterior vaginal wall prolapse. Scoring system of PFDI-20 was from 59.150 ± 13.143 preoperatively to 8.400 ± 4.749 postoperatively and PFIQ-7 was from 73.350 ± 32.281 to 7.150 ± 3.110, while PISQ-12 was from 15.825 ± 4.050 to 12.725 ± 3.471.
Conclusions: QOL and the degree of subjective satisfaction were significantly improved postoperatively. Anterior repair deserves more attention because of the higher recurrence rate. The long-term follow-up of the patient is warranted to draw firm conclusion.

Key words: Lower Urinary Tract Symptoms; Pelvic Organ Prolapse; Quality of Life; Recurrence; Small Intestinal Submucosa

Introduction

Pelvic organ prolapse (POP) is a major health concern that affects a number of women, especially the elderly female. Patients with severe POP usually have a combination of anatomic abnormalities, involving the anterior, posterior, apical vagina, and the uterus. The incidence of women undergoing surgery becomes higher.[1] Over the past decades, the prevalence of recurrent rate 1 year after traditional pelvic reconstructive surgery has been reported at about 58%.[2] Facing the high recurrence rates and hoping to reduce the rates of reoperation, surgeons have increasingly used mesh to correct POP, especially meshes made of synthetic materials. We placed mesh into the vesicovaginal and rectovaginal spaces, restoring Levels I and II vaginal support. However, the complications associated with the synthetic mesh materials (e.g., mesh erosion, vaginal infection, dyspareunia and chronic pain) seriously affect the women's quality of life (QOL).[3] Thus, an ideal mesh material is needed urgently.

The use of porcine small intestine submucosa (SIS; Cook Medical) mesh has recently been reported,[4] but no large-scale prospective study has been published. Our study aimed to analyze the anatomic outcomes and QOL in

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a population of POP patients who underwent SIS surgical repair. The postoperative follow-up was 3-12 months.

Methods

This prospective study included forty consecutive patients undergoing pelvic reconstructive surgery with SIS between March 2012 and December 2013 at a tertiary teaching hospital in Beijing, China. We ensured the number according to the calculation method of sample size. The margin of error is 12%, taking the lost follow-up and the accidental death into consideration. Ethical approval for this study was granted by the Ethics Committee of Peking University People's Hospital and the reference number was 2013-ethic-05. Written informed consent was obtained before sample collection.

The inclusion criteria were the presence of stage ≥2 POP confirmed by POP quantification (POP-Q) and the presence of more than one symptom associated with prolapse (sense of vaginal bulging, lower urinary tract symptoms [LUTS], fecal incontinence, vaginal pain, and dyspareunia). The patients' POP-Q score was ensured by more than two physicians. We excluded patients with age <18 years, body mass index >40 kg/m^2, infection, prior pelvic mesh surgery, collagen disease, and cancer. The patients who were unable to tolerate the anesthesia were also excluded from the study. We recorded the pre-, intra-, and postoperative characteristics. Baseline demographics consisted of age, sexual activity, childbearing history, comorbidities, surgical history, and the surgical procedure. Preoperative assessment included an interview and prolapse quantification by the POP-Q system, 1-h Pad test, and urodynamic examination. We focused on LUTS, including abnormal frequency of micturition, urgent urination, cough (or sneezing) leakage, dysuria, and urinary incontinence. We defined the abnormal frequency of micturition as urinating more than six times in the daytime or two times at night. In addition, we concentrated on patients' most severe symptom of LUTS.

The SIS mesh augmented surgery was performed under general or spinal anesthesia, with patients in the lithotomy position and with an indwelling urinary catheter. The specific operative steps were as follows: First, 40 ml epinephrine in saline (1:200,000) was injected into the vesicovaginal space, and a midline vaginal incision was made from the bladder neck to the anterior fornix. The tendinous arch of the pelvic fascia (white line) was touched by sharp and blunt separation of the vesicovaginal space. Being guided by the left index finger in the rectum, the surgeon took hold of the bilateral uterosacral ligament through the anterior fornix and marked it with a suture. Next, a 7 cm × 20 cm four-layered SIS mesh was divided into two parts to repair the anterior and posterior walls. For the anterior compartment, one 7 cm × 8 cm four-layered SIS mesh was cut into a trapezoidal shape with two arms (each arm length was 2 cm) which were fixed to the bilateral uterosacral ligaments. The up middle point of the mesh was sutured to the anterior cervix with 1-0 coated VICRYL Plus Antibacterial Sutures. The distal part of the mesh was sutured to the bladder neck, and the mesh was attached to the tendinous arch of the pelvic fascia by absorbable sutures bilaterally. Finally, the anterior wall incision was closed using continuous hemstitch sutures.

For the posterior compartment, the repair began with injecting 60 ml epinephrine in saline (1:200,000) into the rectovaginal space. We then made a longitudinal posterior wall incision, beginning below the posterior fornix and ending at the hymen. Blunt and sharp dissections were continued to expose the ischial spine and sacral spine ligament. The anterior rectal fascia was sutured with the interrupted vertical mattress suture. The shape of the posterior mesh was similar to that of the anterior mesh, except for the longer length of the two arms (3 cm). The up middle point of the mesh was fixed onto the posterior wall of cervix or the apical posterior wall (in case of hysterectomy) and the bilateral uterosacral ligament, the two arms were sutured to bilateral sacrospinous ligaments. The distal portion was then trimmed and attached snugly to the anal levator muscle, which was close to the perineal body fascia. Tacking sutures were placed to close the posterior vaginal incision.

The operative details had been described in a previously published article and in the product instruction manual.[5] Additional procedures were undertaken if necessary. Transvaginal hysterectomy (TVH) was conducted if patients had uterine diseases (e.g., hysteromyoma and uterine adenomyosis). Stress urinary incontinence (SUI), diagnosed by 1-h Pad test and urodynamic evaluation, was treated with tension-free vaginal tape-obturator (TVT-O). Vaginal packing was kept about 24 h postoperatively. The Foley catheter was removed 72 h after the operation, using ultrasonography to measure the residual urine volume. Urinary retention was defined as residual volume >100 ml. We recorded the operative time and the intraoperative bleeding volume. The intraoperative and postoperative complications were also listed.

The women were asked to visit the gynecological clinic at 3, 6, and 12 months postoperatively. The follow-up included the subjective feeling, the status of surgical wound healing, the presence of infection or erosion, bowel movements, the LUTS status, and the POP-Q score results. In addition, the patients completed the pre- and post-operative QOL questionnaires (Pelvic Floor Distress Inventory [PFDI]-20 and Pelvic Floor Impact Questionnaire [PFIQ]-7) by face-to-face interview, which were previously validated for using in POP patients.[6,7] Moreover, participants were required to answer a sexual function questionnaire (Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire [PISQ-12]).[8] All cases finished the questionnaires without shedding.

Objective success was defined as POP-Q stage 0 or 1 in all compartments. Thus, objective recurrence meant postoperative stage ≥2 (POP-Q) in any compartment. Subjective success was defined as having no more than an asymptomatic bulge protruding beyond the hymen and has no recurrence of symptoms. Subjective recurrence implied

there was a symptomatic bulge beyond the hymen and recurrence of symptoms.

SPSS software (version 17.0; IBM, Armonk, NY, USA) was used for statistical analyses. Descriptive statistics were used for data analysis. Categorical variables were presented as frequencies and percentages. Continuous variables were summarized using mean and standard deviation. All data were tested for normality of distribution, median (P_{25}, P_{75}) were used to analyze the abnormal distribution. Pre- and post-operative POP-Q and QOL scores were compared using repeated measures data of ANOVA. The postoperative recurrence rates were compared by linear-by-linear association of Chi-square test. $P < 0.001$ was considered to indicate statistical significance. $P \geq 0.001$ was considered to indicate a trend.

Results

A total of 40 patients met the inclusion criteria, and none of them were lost to follow-up. The mean age of the patients was 58.38 ± 9.87 years. The follow-up time was 1 year. All patients had a history of vaginal delivery. The median parity was 2. Among them, one patient had a history of precipitate delivery, one received midwifery forceps, and four experienced perineal laceration during delivery. Two patients had done heavy labor early after delivery. Three patients had received hysterectomy because of benign disease. Thirty-nine patients had stage 3 prolapse. In terms of LUTS, 14 patients (35%) were diagnosed with SUI, four patients had the symptoms of mixed urinary incontinence (MUI), and two patients had urge urinary incontinence (UUI). Ten patients only suffered from the prolapse of the vagina, without LUTS.

The intraoperative related data were shown in Table 1. One patient underwent SIS anterior wall repair surgery with SIS and two underwent posterior wall repairs. The other 37 patients underwent total repair (both anterior and posterior). The mean estimated blood loss and the average operative time were collected. In all, 18 patients underwent TVH surgery because of uterine disease. One woman had anus sphincter reconstruction because of defecation urgency. Five patients with prolonged cervix underwent Manchester operation and 14 patients diagnosed with severe urinary incontinence had TVT-O. There was no blood vessel or organ damage.

Table 1: Surgical baseline data of the patients

Variables	Results
Operative time (min)	124.40
Intraoperative bleeding volume (ml)	129.52
SIS procedure, *n* (%)	
Anterior	1 (2.5)
Posterior	2 (5.0)
Total	37 (92.5)
Concomitant surgeries, *n* (%)	
TVH	18 (45.0)
Manchester	5 (12.5)
TVT-O	14 (35.0)
Rectectomy	1 (2.5)
Catheter retention time (days), mean ± SD	4.71 ± 1.29
Residual urine volume (ml), median(P_{25}, P_{75})	11 (6,17)
Postoperative temperature (°C), mean ± SD	37.71 ± 0.51
Duration of hospitalization (days), mean ± SD	9.85 ± 3.13

TVH: Transvaginal hysterectomy; TVT-O: Transvaginal tension-free vaginal tape-obturator; SD: Standard deviation; SIS: Small intestinal submucosa.

The average time of Foley indwelling catheter after the surgery was 4.71 ± 1.29 days. The residual urine volume was used to evaluate postoperative bladder recovery. Three of the patients had urinary retention and underwent indwelling catheter again. Two of the patients had the bladder function recuperated for <7 days. One patient still suffered from dysuria after 14 days catheter indwelling and she underwent a second procedure of graft release. After that, her urinary function recovered. Six patients suffered from postoperative fever with the temperature above 38.5°C, which was defined as postoperative pyrexia. We changed the antibiotic and the patients' temperature returned to normal. None of the patients developed a postoperative infection during the hospital stay.

The mean points in the POP-Q system including Aa, Ba, C, total vaginal length (TVL), Ap, Bp, and D were shown in Table 2. It should be noted that 26 patients had no point D because of hysterectomy. When comparing the pre- and post-operative (3, 6, and 12 months) points, the statistical differences were significant, except for TVL. The degree of vaginal and uterine prolapse was improved after the surgery.

Figure 1 summarizes the patients in regard to LUTS. Of the thirty patients who suffered from LUTS preoperatively, ten SUI and four MUI patients underwent TVT-O surgery simultaneously. Among them, nine patients announced that the symptoms were completely relieved, and two patients proved improvement. The other three patients claimed no improvement. Moreover, four patients with mild SUI did not undergo TVT-O surgery because the symptom did not affect their daily life. The UUI in two patients was resolved with tolterodine tartrate. Ten patients who experienced abnormal frequency of micturition or dysuria had no concomitant procedure, and six patients' symptoms were diminished postoperatively. The other four patients claimed no improvement or a worse outcome. Postoperatively, no one developed new symptoms including the ten patients who had no LUTS preoperatively.

During the first 3 months postoperatively, the objective recurrence rate was 9/40. Two of the nine women complained vaginal bulge and voiding difficulty. The other seven patients had no symptoms, which indicated subjective success. The subjective recurrence rate was 2/40 ($n = 2$). The recurrence rate of prolapse was higher anteriorly than posteriorly. At 3 months postoperatively, the recurrences all occurred in the anterior layer. At 6 months, however, 15 patients (37.5%) experienced recurrences mostly in the anterior compartment.

Table 2: Pre- and post-operative POP-Q of the patients

Items	Preoperative POP-Q	Postoperative POP-Q			*F*	*P*
		3 months	6 months	12 months		
Aa	1.75 (0,2)	-2 (-3,-1)	-2 (-2,0)	-2 (-2,0)	89.144	0.000
Ba	3.25 (2,4.88)	-2 (-3,-1)	-2 (-2,0)	-2 (-2,0)	124.298	0.000
C	2 (-1,3.75)	-7 (-7,-6)	-7 (-7,-6)	-7 (-7,-6)	130.789	0.000
D	-2.25 (-3,-1)	-6 (-7.38,-2.25)	-7 (-7,-6)	-7 (-7,-6)	44.185	0.000
Ap	0 (-1,1)	-3 (-3,-2)	-2 (-3,-2)	-2 (-2,-2)	48.648	0.000
Bp	0 (-0.75,2)	-2.5 (-3,-2)	-2 (-3,-2)	-2 (-3,-2)	65.264	0.000
TVL	8 (7,8)	8 (7,8)	8 (7,8)	8 (7,8)	0.494	0.486

All data were shown as median (P_{25},P_{75}). POP-Q: Pelvic organ prolapse quantification; TVL: Total vaginal length.

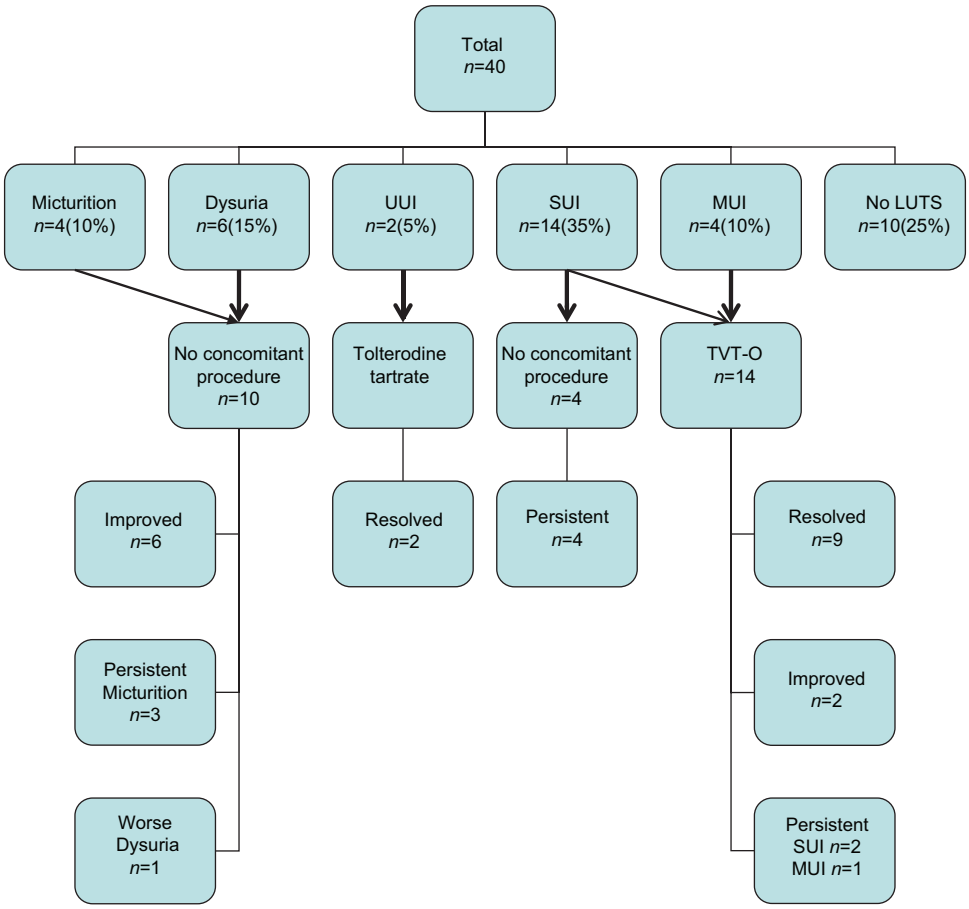

Figure 1: Flow chart of changes in the lower urinary tract symptoms after different treatments: no concomitant procedure or medicine, concomitant TVT-O, and tolterodine tartrate. SUI: Stress urinary continence; MUI: Mixed urinary incontinence; UUI: Urge urinary incontinence; TVT-O: Transvaginal tension-free vaginal tape-obturator.

Two patients had a posterior wall prolapse, and one had an apical prolapse. However, the subjective recurrence rate was only 3/40 ($n = 3$). At the 12-month follow-up, 16 patients had anterior wall prolapse, but only two of them had a posterior wall prolapse, and one had an apical prolapse. Only three patients had symptoms. The other 37 patients were satisfied with the procedure. The objective recurrence rate was 16/40, while the subjective recurrence rate was only 3/40. There is no statistically significant difference in both objective and subjective recurrence rates between 3-month, 6-month, and 12-month follow-ups ($P > 0.001$).

During the 1st month postoperatively, one patient was diagnosed with ulcerative colitis because of hematochezia and was cured by drug therapy. One patient had anus sphincter reconstruction surgery because of defecation urgency after 1 month postoperatively. One patient experienced moderate vaginal pain 15 days after surgery and infection was detected in the posterior vaginal wall where the mesh had been implanted. The symptom disappeared after using estrogen-containing vaginal suppository and estrogen cream to accelerate the repair of the vaginal mucosa, combining with the oral antibiotics. At the 12-month

follow-up, one patient received a secondary surgery with a Bard Mesh (TVM, Avaulta; C.R. Bard, Murray Hill, NJ, USA) because of stage 3 anterior prolapse and dysuria. No SIS erosion occurred in any of the forty patients.

All patients filled the pre- and post-operative scoring questionnaires (PISQ 12, PFDI-20, and PFIQ-7). Based on data from the PISQ-12 scores, 15 patients had no sexual activity for more than 1 year preoperatively because of lowered sexual desire and the prolapse. Among them, two patients recovered sexual activity after surgery. In the 25 patients with sexual activity, four patients claimed that their sexual QOL had decreased, largely because of the LUTS, there was no physical findings that can explain their symptoms. Five patients believed that their sexual QOL had improved, and the others felt no significant change. Thus, there was no significant difference between pre- and post-operative data in sexual QOL ($P \geq 0.001$) (i.e., their postoperative sex lives had not improved). When compared with the preoperative data, the 3-, 6-, and 12-month PFDI-20 scores were significantly decreased [Table 3], as showed with the PFIQ-7 scores. The statistics revealed that surgery improved the QOL.

Discussion

In 2003, Cosson *et al*.[9] suggested that the ideal pelvic mesh should include the following characteristics: better tissue compatibility, greater chemical inertness, decent elasticity and tension, low possibility of infection, low rate of rejection, and morphologic plasticity. Until now, no mesh could match all these features. The pelvic meshes consisted of prosthetic materials and biologic grafts. During the past decades, prosthetic materials had been widely used to correct POP, but they were associated with a high rate of complications, seriously affecting the QOL.

Gynecologists have long used biologic grafts from other species (xenografts) to repair hernias and reconstruct the pelvis.[10] It was thought that these tissues could reduce the complications of erosion, granulomas, and infection with permanent prosthetic materials.[11]

SIS, derived from the submucosa of porcine small intestine, is an acellular, three-dimensional lattice of collagen and extracellular matrix, not cross-linked. The extracellular matrix can carry biologic signals, which encourages host angiogenesis as well as connective tissue and epithelial differentiation and growth, finally replacing the graft with constructive connective tissue remodeling instead of scar tissue.[12] SIS, being freed from cellular components, has a low rate of rejection because it is incorporated into the host tissue with no significant immunologic reaction. Particularly, there has been no evidence of a chronic inflammatory reaction.[13] The findings were confirmed by a comparative study in an animal model that evaluated the incorporation of four biologic sling materials, including cadaveric fascia lata, cadaveric dermis, porcine dermis, and SIS.[14] The study suggested that SIS has biocompatibility that is superior to other biologic materials.

Few studies have reported the use of SIS for treating POP. A case − control study consisting of 14 women who underwent traditional anterior repair and 14 women who underwent anterior repair with an SIS graft (SG) were reported by Chaliha *et al*.[15] At their 6-month follow-up, SG repair had significantly improved all POP-Q measurements except TVL, whereas traditional repair improved some measurements (Aa, Ba, C, Ap, and Bp) but not others (D, TVL, gh, and pb). The study did not distinguish the anterior wall from the posterior wall and lacked randomization. Feldner *et al*.[16] reported a randomized controlled trial that compared SGs with the traditional colporrhaphy (TC) for the treatment of anterior vaginal prolapse. Patients were randomly assigned to SIS ($n = 29$) or to TC ($n = 27$) preoperatively, and outcomes were analyzed at 12 months postoperatively. The SIS group had 86.2% anatomic cure compared with 59.3% for TC ($P = 0.03$). SIS repair improved point Ba significantly, and there were no differences between the techniques in regard to QOL. These studies largely focused on anatomic cure or recurrence, not the subjective recurrence. Our study was a prospective study. We defined anatomic cure as objective success, whereas subjective success was defined as no symptoms and no bulge beyond the hymen. We then analyzed the postoperative subjective and objective success and recurrence rates. In addition, we also focused on the LUTS.

Most of our forty patients underwent both anterior and posterior vaginal wall repair. The SIS surgery improved patients' postoperative POP-Q measurements. Points Aa, Ba, C, Ap, Bp, and D (but not TVL) were significantly different, which was similar to the results of the Chaliha *et al*.'s study.[15] The results showed that the objective recurrence rate was much higher than the

Table 3: The changes of PISQ-12, PFDI-20, and PFIQ-7 scores between baseline and after pelvic reconstructive surgery with SIS ($n = 40$)

Item	Preoperative	Postoperative			*F*	*P*
		3 months	6 months	12 months		
PISQ-12	15.825 ± 4.050	13.625 ± 3.933	12.475 ± 3.343	12.725 ± 3.471	51.921	0.001*
PFDI-20	59.15 ± 13.143	22.45 ± 12.914	15.35 ± 8.110	8.400 ± 4.749	276.269	0.000
PFIQ-7	73.350 ± 32.281	19.650 ± 8.192	9.275 ± 4.070	7.150 ± 3.110	166.811	0.000

*$P \geq 0.001$ means no significance. PISQ-12: Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire-12; PFDI-20: Pelvic Floor Distress Inventory-20; PFIQ-7: Pelvic Floor Impact Questionnaire-7; SIS: Small intestinal submucosa.

subjective recurrence rate. Most of the recurrent patients had no related symptoms and these patients did not require repeat treatment. The anterior recurrence rate was higher than the posterior recurrence rate, similar to the study of Armitage *et al*.[17] This result was possibly relevant to the unidentified defect during operation. Nevertheless, previous studies reported that the recurrence rate of synthetic mesh repair was 4%–15%,[18,19] which was much lower than that after SIS repair. The reason for the variance might be the better stability of synthetic mesh. The SIS repair, however, had no erosion because of the better biocompatibility and patients' subjective degree of satisfaction was much higher.

In our results, one patient underwent the graft release surgery because of urinary retention 10 days after SIS repair. One patient had anus sphincter reconstruction surgery because of defecation urgency and the symptom was not relevant to the SIS surgery. In addition, one woman experienced infection in the posterior vaginal wall where mesh had been implanted and had severe vaginal pain, the pain disappeared after being treated with a vaginal suppository containing estrogen and with estrogen cream. At the 1-year follow-up, the patients' LUTS was largely relieved. Only one patient underwent secondary surgery with Bard Mesh (TVM, Avaulta) because of stage 3 anterior prolapse and dysuria. The other patients with recurrences required long-term follow-up to determine if they would need another operation.

Significant improvement in the QOL was also observed. SIS repair benefited the patients by improving their QOL, but it did not bring significantly improved sexual function according to PISQ evaluation. Two patients recovered sexual activity after surgery and four patients believed that their sexual QOL had decreased. This may be due to the older age of our patients, who may believe sex life quality is not as important as in younger patients.

Our study shows the clinical effectiveness of SIS. However, the study has certain limitations, including the limited number of samples and the lack of randomized control group. Perhaps, we need long-term follow-up data, but the statistics show our results and conclusions to be solid.

In conclusion, SIS has better biocompatibility with human tissues than synthetic mesh. It can reduce the complications associated with synthetic mesh but not the objective recurrences. Our subjective recurrence rate was 5.0%−7.5%, which was much lower than the objective recurrence rate (22.5%−40.0%). The results show that QOL can be improved, with a much higher degree of subjective satisfaction. Postoperative TVL was not shortened. Thus, SIS can be used in young women, but care must be exercised when performing an anterior repair. Based on our results, we believe that monitoring the long-term clinical effect on patients is warranted.

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Conflicts of interest

There are no conflicts of interest.

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