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Safety and efficacy of a self-developed Chinese pelvic repair system and Avaulta repair system for the treatment of pelvic organ prolapse in women

A multicenter, prospective, randomized, parallel-group study

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Abstract

The pelvic organ prolapse (POP) repair systems used in China are imported and expensive. Our aim was to compare the efficacy and safety of a self-developed pelvic floor repair system versus the Avaulta system.

This was a multicenter, randomized, parallel-group, noninferiority trial of 132 patients with POP stage ≥II from the Tongji Hospital Affiliated to Tongji University and the General Hospital of Ningxia Medical University enrolled from 02/2014 to 03/2015. The patients were randomized 1:1 to POP repair using the self-developed system or the Avaulta system. Perioperative conditions, POP quantification, pelvic floor impact questionnaire-7, and prolapse quality of life questionnaires, gynecological ultrasound, and postoperative complications were compared. Patients were followed at 1.5, 3, and 6 months.

According to the POP quantification scores obtained at 6 months after surgery, the cure rates of the self-developed and Avaulta groups were 98.3% and 100.0%, respectively ($P > .999$). At 6 months follow-up, the pelvic floor impact questionnaire-7 scores of the self-developed and Avaulta groups were both improved ($P < .001$ vs baseline), with no between-group difference observed ($P = .488$). There were no differences between the 2 groups for subjective symptoms of POP (all $P > .05$). There were no significant differences between the 2 groups regarding complications (all $P > .05$).

The self-developed pelvic reconstruction system is safe and effective for the treatment of POP and improves the patients' quality of life, without difference compared to the Avaulta system.

Abbreviations: PFIQ = pelvic floor impact questionnaire, POP = pelvic organ prolapse, POP-Q = POP quantification.

Keywords: mesh, pelvic floor functional recovery, pelvic organ prolapse, pelvic reconstruction, prospective study, quality of life

1. Introduction

Pelvic organ prolapse (POP) is the descent of pelvic organs toward or through the vagina due to loss of connective tissue strength and muscular support, resulting in pelvic organs displacement and abnormal organ locations and functions.[1–3] The main symptoms of POP are pelvic organ prolapse, vaginal bulge, abnormal urination and defecation, vulvar bleeding and inflammation, all affecting the quality of life of the patients to varying degrees.[1–3] In the Netherlands, POP is very common in middle-aged and elderly women, with an incidence rate of 40%, but only 12% of them have discomfort symptoms.[4] In the

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YO and RC contributed equally to this work.

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United States, POP of at least stage I is found is ≥70% of women 18 to 83 years old attending a gynecological clinic,[5] and the estimated weighted prevalence of symptomatic POP is 2.9%.[6] In China, a study revealed that among women 22 to 78 years old attending a gynecological clinic for routine examination, 97% of women had asymptomatic mild anterior vaginal wall descent, but without meeting the criteria of POP.[7]

Supportive or space-occupying vaginal device (pessary) may be used for any stage or site of POP to reduce prolapse inside the vagina, support pelvic structures, and relieve pressure on bladder and bowel.[1–3] Vaginal or transabdominal hysterectomy, and vaginal anterior and posterior wall repair have long been the main treatments of POP,[1–3] but the recurrence rate of non-mesh repairs such as colpectomy or transvaginal hysterectomy with or without anterior and/posterior colporrhaphy is 29% to 30%.[8–11] In recent years, transvaginal mesh for pelvic floor reconstructive surgery has been introduced.[8] The advantages of the transvaginal mesh include restoring the anatomical structure of the pelvic floor, minimal invasiveness, uterus retaining, and recurrence rates.[12] Nevertheless, over time, some shortcomings have been exposed, and the common complications include mesh erosion, pelvic pain, and pain during sexual intercourse.[9,13]

The Prolift pelvic floor repair system was introduced on the market in 2005.[14] It is a finished box containing mesh with specific size and shape, and the corresponding puncture device. Around the same time, a large number of similar products became available on the market, such as the Apogee, Perigee, and Avaulta repair systems.[13] A study reported that the objective cure rate of POP using a transvaginal mesh technique was 87%.[15] Specific size and shape of mesh and standardized puncture procedure simplify the operation process and make mesh implants more accurate and reliable.

At present, the box sets used in China are all imported and are expensive. Therefore, the economic burden on the patients is heavy, resulting in low popularity of the box sets in China. In order to solve this issue in the current medical market in China, a completely localized pelvic floor repair system was independently researched and developed by Professor Xiaowen Tong from Tongji Hospital Affiliated to Tongji University jointed with Condiner Medical Technology Co., Ltd., Changzhou, China. The localized pelvic floor repair system contains a mesh for pelvic floor repair and the corresponding surgical instrument.

Therefore, the aim of the present study was to observe the clinical efficacy and safety of this self-developed pelvic floor repair system using a multicenter prospective noninferiority study conducted at the Tongji Hospital Affiliated to Tongji University and the General Hospital of Ningxia Medical University. The self-developed pelvic floor repair system was compared with the Avaulta repair system.

2. Materials and methods

2.1. Materials

2.1.1. Study design and subjects. This was a multicenter, randomized, parallel-group, noninferiority trial of 132 patients with POP stage ≥II from the Tongji Hospital Affiliated to Tongji University and the General Hospital of Ningxia Medical University enrolled from February 2014 to March 2015. This study was approved by the ethics committees of Tongji University and the General Hospital of Ningxia Medical University. All patients signed a written informed consent.

The surgical indications for POP were:

(1) POP stage ≥II; and
(2) obvious symptoms of POP.

The inclusion criteria were:

(1) agreed to participate in the trial and signed the informed consent;
(2) female patient of 35 to 85 years of age;
(3) pelvic floor dysfunction and POP stage ≥II that required pelvic reconstructive surgery;
(4) normal heart, liver, and kidney functions as indicated by clinical and laboratory examinations; and
(5) able to communicate well with the investigators and complied with the study requirements.

The exclusion criteria were:

(1) acute or severe infection;
(2) metabolic disorders, immune dysfunction, or substance abuse;
(3) hematopoietic system, endocrine system, or any other serious primary diseases or mental illness;
(4) allergic to implant or a variety of drugs, or patients with allergic constitution;
(5) malignant disease of uterine appendages;
(6) pregnant or lactating women; or
(7) unwilling or unable to restrict activities or follow the doctor's advice.

2.1.2. Self-developed repair system. The localized pelvic floor repair system (developed by Professor Tong Xiaowen from Tongji Hospital Affiliated to Tongji University and manufactured by Condiner Medical Technology Co., Ltd) included the mesh and the corresponding surgical instrument (Supplementary Fig. 1, http://links.lww.com/MD/E887). This system has been approved for clinical use in China. The principle was to provide mechanical support by implanting the mesh, and induce the formation of new fibrous connective tissues to form pelvic floor supporting tissues for pelvic floor reconstruction. The total pelvic floor repair system (model number: QP590 × 250-B-P/QX-B), anterior pelvic floor repair system (model number: QB590 × 120-B-P/QX-B), and posterior pelvic floor repair system (model number: HB280*140-BI-P/QX-B) were used as required.

The mesh is made of medical polypropylene monofilament (thickness: 0.4 mm; hole size: 3.5 mm; porosity ≥75%; weight: 45 g/m^2; and connection strength ≥16 N). The main body of the instrument is made of stainless steel. The repair system is delivered sterile and as a single-use disposable clinical instrument; it cannot be sterilized twice. The Avaulta repair system used in the Avaulta group was purchased from C.R. Bard Inc. (Billerica).

2.2. Grouping and blinding

The patients were randomly divided into 2 groups (the self-developed device group and Avaulta group). Randomization was undertaken by a third-party company using a web-based and telephone system. In this study, the patients and the postoperative assessors (who did not participate in surgery) were blinded to grouping.

2.3. Preoperative preparation

After obtaining the patient's detailed medical history and recorded the complications and history of previous pelvic

surgeries, gynecologic examination, POP Quantification (POP-Q) questionnaire, pelvic ultrasound examination, cytological examination of cervical/vaginal stump, determination of bladder capacity and residual urine, urinary incontinence induced/finger pressure test, and other routine preoperative examinations (blood routine test, hemagglutination test, hepatorenal function, urine routine test, electrocardiogram) were performed. Patients with internal diseases were provided with effective symptomatic treatments. For patients with ulcerated prolapsed area, the wounds were disinfected with iodine daily, and locally applied with recombinant human epidermal growth factor. The vagina was packed with painless iodine gauze after the prolapse was restored and surgery was performed after local inflammation resolution. The patients were given oral laxatives on the day before surgery and enema in the morning on the day of surgery. Antibiotics (first generation cephalosporins) were used to prevent infections from 30 minutes before surgery to 72 hours after surgery.

2.4. Surgery

The surgery was performed under general anesthesia or combined spinal epidural anesthesia, at the anesthesiologist's and surgeon's discretion. All surgeries were performed by the same 3 doctors, including 1 chief surgeon at each center. The patients in the 2 groups underwent pelvic floor reconstructive surgery. Patients with anterior and middle pelvic defects received anterior pelvic floor reconstructive surgery. Patients with mild posterior vaginal wall prolapse underwent posterior vaginal wall repairs. Patients with severe posterior pelvic defect received posterior pelvic reconstructive surgery. Elderly patients with hysteromyoma, adenomyosis, and other organic lesions received transvaginal hysterectomy. Surgery for incontinence was not performed on patients complicated with stress incontinence.

In the self-developed system group, the first step was to implant the mesh. After the anesthesia takes effect, the saline is injected into the submucosa of the anterior/posterior vaginal wall to form a "water cushion." The anterior/posterior vaginal wall was cut lengthwise with surgical scissors, and the vesicovaginal/rectovaginal space was separated to reach the ramus inferior ossis pubis/sacral spine ligament on both sides using blunt dissection technique. The mesh for total pelvic floor repair consisted of 6 fixation bands, of which 4 bands were used to fix the anterior pelvic floor mesh placed in the vesicovaginal space through the obturator, and the other 2 bands were fixed to the sacral spine ligament by hip puncture. The 2 fixation bands could also be directly placed into the rectovaginal space after trimming. The mesh for anterior pelvic floor repair consisted of 4 fixation bands, which were used for fixation through the obturator. The mesh for posterior pelvic floor repair was fixed to the ligamenta sacrospinosum by puncture or directly placed into the posterior wall of the vagina after trimming. The mesh (without specific shape) was cut and shaped by the surgeons according to the actual situation. The second step was to adjust the position of the implanted mesh. The position of the mesh was adjusted by fixation bands to make sure that the mesh was not in a state of tension. When the mesh was put in the right place, the exposed mesh outside the skin was trimmed to the dermis.

In the Avaulta group, the Avaulta repair system (C.R. Bard Inc.) was used according to the product monograph.

2.5. Follow-up and evaluation indexes

Operative time, blood routine test, routine urine and biochemical indexes, conditions of wound healing, and intraoperative and postoperative complications were recorded.

The patients were followed up at 1.5, 3, 6, and 36 months after surgery. The POP-Q questionnaire was the primary outcome. It was used before surgery and during follow-up. The Chinese version has been previously validated.[16] The patients were asked if there were any postoperative complications such as infection, mesh erosion, lower limb pain, new onset of urinary incontinence, constipation, and so on. POP-Q $\leq$I within the first 6 months of follow-up after surgery was considered as effective. POP-Q $\geq$II within 6 weeks of follow-up was considered as ineffective. POP-Q $\geq$II beyond 6 weeks of follow-up was considered as recurrence.

The subjective efficacy questionnaire was completed at the 6-month follow-up. The pelvic floor impact questionnaire short form (PFIQ-7) was used to evaluate postoperative pelvic floor function compared with baseline[17] (validated in Chinese[18]). The questionnaire has 3 subscales: voiding impact questionnaire, colorectal/anal impact questionnaire, and POP questionnaire. Each question was scored as: 0 point for no effect on quality of life, 1 point for mild effect, 2 points for moderate effect, and 3 points for severe effect. The score was calculated as the total score of the 3 subscales divided by the total number of questions $\times$ 100 $\div$ 3; the final score ranges from 0 to 100 points. The higher the score, the larger the impact of symptoms on the quality of life.

The prolapse quality of life questionnaire was used to evaluate the postoperative quality of life compared with baseline[19] (validated in Chinese[20]). The questionnaire contains 9 parts: health status, life impact, role constraints, physical strength, social intercourse, personal relationship, emotion, sleep, and severity of POP.

2.6. Sample size calculation

This study aimed to verify whether the clinical cure rate of the self-developed pelvic reconstruction system was not inferior to the imported product (Avaulta). Randomization was 1:1. Qualitative indexes were used as the evaluation indexes. Using $\alpha = 0.05$, $\beta = 0.2$, noninferiority criteria of $\delta = 0.1$ (the drop-out rate was determined as 10% after discussion among the investigators), and average effective rate of $P = 95\%$,[12] and according to the formula $N = 12.365 \times P\,(1\text{-}P)/\delta^2$, the sample size was calculated as 58 in each group. Taking into account a drop-out rate of 10%, 64 patients were planned for recruitment in each group (128 in total).

2.7. Statistical analysis

SPSS 20.0 (IBM, Armonk, NY) was used to process the data. Continuous data are presented as mean $\pm$ standard deviation or median (minimum, maximum), as appropriate. Categorical data are expressed as absolute numbers and proportions. The Student t test or the Mann–Whitney U test was used to compare the continuous data between the 2 groups, while the Fisher exact test was used for categorical data. The paired t-test or the Wilcoxon signed-rank test was used to determine the changes in questionnaire scores before/after surgery. Two-sided $P < .05$ was considered significant. The full analysis set included all patients who completed at least 1 follow-up visit. The per-protocol set included all patients who completed the study

according to the protocol. The safety set (SS) included all patients who received a mesh. Unless specified otherwise, all data presented are from the per-protocol set, except the adverse events, which were based on the safety set.

3. Results

3.1. Characteristics of the patients

Figure 1 presents the patient flowchart. As shown in Table 1, there were no significant differences between the 2 groups for age, body mass index, and other demographic data.

3.2. Primary outcomes

According to the POP-Q score obtained at 6 months after surgery, the cure rates of the self-developed system and Avaulta groups were 98.3% and 100.0%, respectively. There were no differences at 6 weeks (100.0% vs 100.0%, $P=1.00$), 3 months (98.3% vs 98.2%, $P=1.00$), and 6 months (98.3% vs 100.0%, $P=1.00$). Supplementary Table 1, http://links.lww.com/MD/E888 shows that all postoperative (6 months ± 5 days) ultrasound parameters were similar between the 2 groups.

3.3. Subjective evaluation (secondary outcomes)

Before the operation, the average PFIQ-7 scores of the self-developed system and Avaulta groups were 137.4 and 126.6, respectively. At 6-month follow-up, the average PFIQ-7 scores of the self-developed system and Avaulta groups were 13.6 and 10.3 (both $P<.001$ vs baseline, but $P=0.488$ between groups) (Table 2).

At 6 months after operation in the self-developed system group, 71.2% of the patients considered that POP had no effect on their lives, 27.1% considered that there were only mild effects, and <2% considered that there were still some effects. Frequent or urgency urination symptoms after the operation were significantly improved. There were no significant differences between the 2 groups (all $P>.05$) (Supplementary Table 2, http://links.lww.com/MD/E889).

Table 1

Baseline characteristics of the subjects in the full analysis set.

Items	Self-developed system (n = 65)	Avaulta system (n = 66)	*P*
Age (yr)			
Mean (SD)	64.5 (10.1)	64.4 (9.2)	.939
Min-max	35–85	43–85	
Ethnicity (n, %)			
Han	62 (95.4)	63 (95.5)	>.999
Hui	3 (4.6)	3 (4.5)	
Height (cm)			
Mean (SD)	157 (6)	158 (5)	.278
Min-max	130-168	150-170	
Weight (kg)			
Mean (SD)	58.8 (8.1)	60.7 (8.8)	.201
Min-max	30–77	40–90	
Gravidity (total)			
Mean (SD)	4 (2)	3 (2)	.059
Min-max	1–9	1–9	
Parity (times)			
Mean (SD)	3 (1)	2 (1)	.128
Min-max	1–9	1–6	
Menopause (n, %)			
Yes	58 (89.2)	60 (90.9)	.779
No	7 (10.8)	6 (9.1)	

SD = standard deviation.

At 6-month follow-up in the self-developed system group, patient's role constraints, physical strength, social intercourse, personal relationship, emotion, sleep, and severity of POP were significantly improved: the proportion of "No effect" was 69.5% to 96.6% in the different categories. Because most subjects were geriatric, sexual life was low at baseline. A cross-sectional study shows that 41.26% of women reported engaging in some form of sexual activity in China.[21] Therefore, 72.9% of patients had no sexual activity, 22.0% considered that there was no effect on their sexual life, 4.2% considered that there was "a little" effect, and 0.9% considered that there were some effects (Supplementary Table 3, http://links.lww.com/MD/E890). There were no

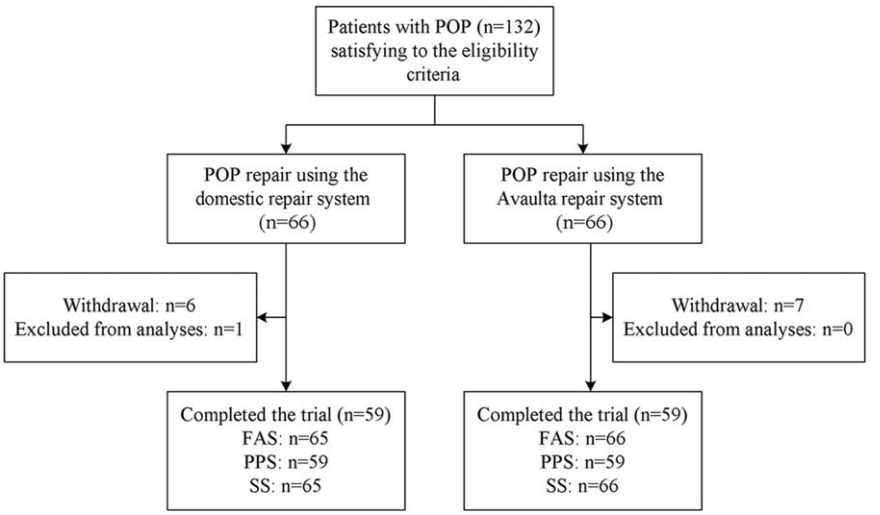

Figure 1. Patient flowchart. FAS = full analysis set, POP = pelvic organ prolapse, PPS = per-protocol set, SS = safety set.

Table 2

Improvements of PFIQ-7 scores after surgery in the per-protocol set.

Items	Self-developed system group (n = 59)	Avaulta group (n = 59)	P
PFIQ-7 score at baseline			.410
Mean (SD)	137.4 (78.0)	126.6 (63.4)	
Min-max	50–300	0–300	
PFIQ-7 score at 6 mo*			
Mean (SD)	13.6 (30.8)	10.3 (20.6)	.488
Min-max	0–167	0–99	

PFIQ = pelvic floor impact questionnaire, SD = standard deviation.
* $P < .01$ compared with baseline values.

differences between the 2 groups (all $P > .05$) (Supplementary Table 3, http://links.lww.com/MD/E890).

The behaviors of addressing POP problems in the 2 groups (use of tampon/pads, prolapse after extrusion, pain or discomfort, and standing up) were similar (all $P > .05$) (Supplementary Table 4, http://links.lww.com/MD/E891).

3.4. Safety assessment

The average operative times for the self-developed system and Avaulta groups were 55 ± 28 minutes (15–160 minutes) and 52 ± 30 (15–160 minutes), respectively. No complications (such as urinary retention, bladder injury, and pelvic hematoma) occurred in the 2 groups. The indwelling urinary catheter was removed 3 days after operation; no dysuria occurred and the wounds healed well (Table 3). Within 1 week after operation, blood routine test, urine routine test, liver and kidney function, and other biochemical tests were not significantly abnormal compared with baseline.

At 6 weeks after operation, there were 4 patients who had develop local infections; 3 patients in the self-developed system group recovered after anti-inflammatory treatment, and 1 patient in the Avaulta group had lasting inflammation. There were 6 cases of mesh erosion or exposure: 4 cases in the self-developed system group and 2 in the Avaulta group. The exposed meshes were removed for 1 or more times, and the pain was relieved for the vast majority of patients. No trend for differences in mesh exposure were observed among the different types of POP or surgeries, but the numbers of events in each subgroup were probably too small for reliable analysis (data not shown; all $P > .05$). After operation, 8 patients in the self-developed system group and 7 in the Avaulta group complained of lower limb pain, but the pain was relieved over time. At 6 months, there were 5 patients with new-onset incontinence (stress urinary incontinence) in both groups, respectively. Six patients developed constipation (2 in the self-developed system group and 4 in the Avaulta group), but the symptoms were improved after taking oral laxative and suppository. At 3 years, 11 patients had secondary incontinence (3 in the self-developed system group and 8 in the Avaulta group) and 11 patients had constipation (4 in the self-developed system group and 7 in the Avaulta group). There were no significant differences between the 2 groups for all complication (all $P > .05$) (Tables 4 and 5).

Table 3

Comparison of the perioperative complications between the 2 groups in the safety set.

Items	Self-developed system group (n = 65)	Avaulta group (n = 66)	P
Operative time (min)			
Mean (SD)	54.85 (28.44)	51.79 (29.58)	.548
Min-max	15.00–160.00	15.00–160.00	
Urinary retention	0	0	1.000
Bladder injury	0	0	1.000
Pelvic hematoma	0	0	1.000
Surgical wound healing			>.999
Perfect	45 (69.2%)	46 (69.7%)	
Good	20 (30.8%)	20 (30.3%)	

SD = standard deviation.

Table 4

Comparison of postoperative complications between the 2 groups.

Items	Self-developed system	Avaulta system	P
Postoperative complications			
6 wk			>.999
N (Missing)	61 (4)	64 (2)	
Yes	16 (26.2%)	16 (25.0%)	
No	45 (73.8%)	48 (75.0%)	
3 mo			>.999
N (Missing)	60 (5)	60 (6)	
Yes	11 (18.3%)	11 (18.3%)	
No	49 (81.7%)	49 (81.7%)	
6 mo			>.999
N (Missing)	59 (6)	59 (7)	
Yes	13 (22.0%)	14 (23.7%)	
No	46 (78.0%)	45 (76.3%)	
3 yr			.606
N (Missing)	50 (15)	48 (17)	
Yes	14 (28.0%)	21 (43.8%)	
No	36 (72.0%)	27 (56.2%)	

4. Discussion

The POP repair systems have to be imported in China and are expensive. Therefore, this non-inferiority study aimed to observe the clinical efficacy and safety of a self-developed pelvic floor repair system compared with the Avaulta system. The results

Table 5

Comparison of postoperative complications between the 2 groups at 6 mo and 3 yr.

	Self-developed system	Avaulta system	P
6 mo	**n = 59**	**n = 59**	
Infections	0	1 (1.7%)	1.000
Mesh erosion	1 (1.7%)	0	1.000
Lower limb pain	8 (13.6%)	7 (11.9%)	1.000
New-onset incontinence	5 (8.5%)	5 (8.5%)	1.000
Constipation	2 (3.4%)	4 (6.8%)	.679
Mesh exposure	3 (5.1%)	2 (3.4%)	1.000
3 yr	**n = 50**	**n = 48**	
Pain	3 (6.0%)	2 (4.2%)	1.000
Discomfort during intercourse	1 (2.0%)	1 (2.1%)	1.000
Repeated bleeding/mesh exposure	1 (2.0%)	2 (4.2%)	1.000
Recurrence	1 (2.0%)	1 (2.1%)	1.000
Secondary urinary incontinence	3 (6.0%)	8 (16.7%)	.205
Constipation	4 (8.0%)	7 (14.6%)	.527
Re-operation	1 (2.0%)	0	1.000

showed that the self-developed pelvic reconstruction system was safe and effective for the treatment of POP. Compared with the Avaulta system, there was no significant difference in efficacy and complications. The quality of life of patients was significantly improved by pelvic reconstructive surgeries using both systems.

In this multicenter prospective randomized non-inferiority controlled trial, the cure rates of the self-developed pelvic floor repair system and Avaulta repair system for the treatment of POP were similar (98.3% and 100%, respectively), indicating that these 2 products had good therapeutic effects. Similar results were obtained for the subjective indicators of quality of life. The results suggest that the self-developed POP repair system was non-inferior to the Avaulta system, which has been shown to achieve good outcomes for the treatment of POP.[22,23]

With regard to safety, complications such as urinary retention, bladder injury, and pelvic hematoma were not observed in the 2 groups. Some patients developed dysuria after indwelling urinary catheter removal 3 days after operation, but the symptoms were relieved when the catheter was pulled out 2 weeks after catheter reset. The estimation of intraoperative hemorrhage volume was subjective, but the hemoglobin levels before and after operations were similar in all patients. The patients had no obvious discomfort symptoms, and there was no progressive decline of hemoglobin level. Intraoperative injury of bladder is usually caused by operator error. In this study, the surgical operators were experienced chief physicians of pelvic floor surgery and no bladder injury occurred.

The complications of mesh in pelvic floor suspension include vaginal mesh exposure/erosion, pain, infection, urination disorders, vaginal scar or contraction,[8,24] of which, mesh exposure/erosion and pain are the most common.[9,25,26] Mesh erosion was defined as any visible vaginal mesh exposure identified on vaginal examination. Several studies have reported that the occurrence rate of mesh exposure/erosion was 0% to 29.7%.[15,25,27] In the present study, 6 patients developed mesh erosion/exposure after operation, including 4 patients (6.2%) in the self-developed system group and 2 (3.0%) in the Avaulta group. The majority of the patients with mesh erosion suffered from a small amount of irregular vaginal bleeding for more than 3 months, and their sexual partners felt pain during sex. Mesh erosion of less than 5 mm is considered to be mild, while mesh erosion of more than 5 mm is severe. The mesh erosion of the subjects in this study was mild and recovered well through local treatment. There were 6 cases of mesh erosion or exposure: 4 cases in the self-developed system group and 2 in the Avaulta group, and wound healed well in 1 to 3 weeks and 1 to 4 weeks, respectively. Patients with mesh exposure are often associated with vaginitis. A small mesh exposure can be removed with a surgical scissors for 1 or more times at the outpatient clinic, and the symptoms caused by mesh exposure for most of the patients were relieved after active treatment of vaginitis and temporarily prohibited sexual life. According to our observation, only erosions smaller than 3 mm in size healed spontaneously under conservative treatment. A study has reported that 0% to 30% of patients developed pelvic pain after pelvic floor suspension surgery.[26] In this study, postoperative pain included pelvic pain and lower limb pain. At 6 weeks after operation, the incidence rates of pain in both groups were 18%, mainly lower limb pain, and patients developed mild symptoms. At 6 months after operation, lower limb pain in the majority of patients was relieved, and only 1 patient complained of significant pelvic and lower limb pain; her vaginal incision healed well, and there were no mesh erosion/exposure or obvious abnormalities during gynecological ultrasound, but the patient had a history of chronic pelvic inflammatory disease; the symptoms were relieved after anti-inflammatory treatment. In this study, no serious complications occurred in both groups.

The present study has limitations. Despite being a multicenter trial and despite the fact that the power analysis showed that the sample size was enough, the sample size was still small. In addition, the follow-up was only of 6 months. Additional studies are necessary to address these issues.

In summary, the application of the self-developed pelvic floor repair system for pelvic floor reconstructive surgery was safe and effective. To a certain extent, it can reduce the economic burden of Chinese patients with POP, achieve satisfying clinical efficacy, and significantly improve the quality of life of the patients. Nevertheless, the surgeons need to master the surgical skills required for pelvic floor repair, and strictly grasp the indications and weigh the pros and cons in order to improve the cure rate and reduce the incidence of complications.

Author contributions

Conceptualization: Yiqin Ouyang, Rujun Chen.
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Writing – original draft: Yiqin Ouyang, Junhua Liang, Xueyu Zhang, Huaifang Li.
Writing – review & editing: Tian Gao, Xiaowen Tong.

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