



## Outcomes of Two Different Meshes for Treatment of POP with a Concomitant Midurethral Sling for SUI: a Retrospective Cohort Study at 2 Years Postoperatively

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### Abstract

**Objective:** Patients had pelvic organ prolapse (POP) often suffered stress urinary incontinence (SUI) simultaneously. We evaluated the outcomes of two different kits, Prosima and Avaulta pelvic repair systems, with a concomitant midurethral sling by treating the disease and compared the efficacies in a single center.

**Methods:** A retrospective cohort study involving 57 consecutive patients underwent either of the two kits followed by tension-free vaginal transobturator tape (TVT-O). The combined surgeries were performed between October 2010 and January 2012. Women who complained bothersome POP had stage II or higher prolapse of anterior vaginal wall were included. All patients were assessed by POP-Q for anatomy, questionnaires for pelvic symptoms and sexual function at 2 years after the surgery. Perioperative outcomes and complications were also recorded.

**Results:** Of 57 women, 29 underwent Prosima and 28 underwent Avaulta meshes procedures. The basic patient demographics and perioperative characteristics were similar between two groups. The number of success were 28 versus 26 ( $P=0.53$ ) at 1 month and 27 versus 26 ( $P=0.97$ ) at 2 years of Prosima and Avaulta groups, respectively. The overall and each scale scores of 3 validated questionnaires were improved significantly from baseline ( $P<0.05$ ), but not different statistically between two groups. Complication rates did not differ significantly from two groups.

**Conclusions:** Both the combined procedures improved POP and concomitant SUI significantly. The efficacy and safety of the two different transvaginal meshes was promising.

### Keywords

Pelvic organ prolapse, Stress urinary incontinence, Mesh, Outcome

### Introduction

Pelvic organ prolapse (POP) often coexists with urinary incontinence, and 19% women will undergo surgery for POP [1]. Moreover, a concomitant anti-incontinence procedure, for example, midurethral sling (MUS), may be applied to cure the concurrent urine leakage. As there isn't standardized definition of success for prolapse

surgery, the estimated success varies widely [2]. However, the surgeons and patients primarily care about not only the restoration of normal anatomy but also the functional improvement in pelvic floor. So sorts of vaginal synthetic meshes emerged in the last decade strived to achieve the goal that improving the health-related quality of women's lives.

Recent years synthetic mesh augmentations for pelvic floor reconstructive operations are increasing in usage and popularity, and it predominates over the autologous muscle and fascia. The short- and long-term result of nonabsorbable mesh has some superiority to standard colporrhaphy. A randomized controlled trial on vaginal anterior wall prolapse with monofilament polypropylene meshes reinforcement has shown its lower anatomic recurrence rate than classic prolapse repair without mesh at 1 year [3]. Another retrospective study also indicated that transvaginal mesh surgery had better anatomic and functional outcomes than colporrhaphy at 4-5 years postoperatively [4]. However, these novel techniques introduce new complications, such as chronic pelvic pain, mesh exposure, and de novo dyspareunia [5-7].

In the present study, two partly different standardized transvaginal meshes, Gynecare Prosima pelvic repair system (Johnson, USA) and Avaulta™ Biosynthetic Anterior support system (Bard, USA), were included to treat patients presented with anterior vaginal wall prolapse accompanied by stress urinary incontinence (SUI). The concomitant SUI was handled by tension-free vaginal transobturator tape (TVT-O) procedure. The role of vaginal mesh kits was to augment the anterior vaginal wall, strengthen the defects of the central and lateral compartment. Prosima repair system with a nonanchored mesh and a vaginal support device (VSD) was invented by Prof. Carrey in 2007 [8] and its advantages comprised smaller dissection area and avoidance of blind puncture. The accessory VSD provided persistent support for vaginal wall and averted mesh displacement caused by increased abdominal pressure or behavior. By contrast, Avaulta repair system was first released into American market at the end of 2005 and it had a trocar-guided transobturator mesh. Within this procedure, 4 skin incisions were required in the groin region.

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Interestingly, many studies have demonstrated that the synthetic meshes were more powerful for treatment of POP than traditional surgery [4,9-11], but seldom compare the efficacy and safety of different mesh procedures. The objective of our research was to assess the results of the two meshes not only at the correction in anatomic reservation but also at symptomatic relief including quality of life and sexuality. Besides, the complications of the two procedures were also taken into consideration.

## Materials and Methods

According to our retrospective design, the data of consecutive patients were abstracted when transvaginal POP repair were performed with either of the two procedures (Prosima and Avaulta pelvic repair system) between October 2010 and January 2012. Both the procedures were performed by two experienced surgeons in our department of Urology. In this study, all the women who complained bothersome POP had stage II or higher prolapse of anterior vaginal wall (according to the Pelvic Organ Prolapse Quantification [POP-Q] system [12]). The concomitant SUI was diagnosed by physical examination and multichannel urodynamics. Routine outpatient visit was done annually if nothing else complications happened. Exclusion criteria included preoperative apical or posterior vaginal wall prolapse, childbirth or pregnant after the POP repair, additional pelvic reconstructive procedure at any time. Institutional research and ethics committee approval for this study was obtained. All women had an indication for surgical correction signed an informed consent before undergoing the operation.

During the outpatient visit, all the patients were examined for anatomy and were asked two questions "Do you usually have a bulge or something falling out that you can see or feel in your vaginal area?" and "Do you experience urine leakage related to coughing, sneezing, or laughing?". Moreover, for this research, all women involved were required to complete the validated questionnaires through telephone or outpatient written form at 2 years following the surgery. The Pelvic Floor Distress Inventory short form-20 (PFDI-20) was used as a symptom-specific questionnaire for pelvic organ prolapse, and the Pelvic Floor Impact Questionnaire-7 (PFIQ-7) was used to evaluate the quality of life [13,14]. Both above questionnaires have three domains that separately assessed subjective prolapse, urinary, and colorectal symptoms. Sexual function was measured by the Prolapse/Urinary Incontinence Sexual Questionnaire short form-12 (PISQ-12) for sexually active women [15]. The success was defined objectively and subjectively. It included: (1) POP-Q stage 0 or I (i.e. no prolapse at or below a point 1 cm above the hymen at any vaginal site) without further surgical intervention; (2) no vaginal bulge or incontinence symptoms. Women who failed this criterion or answered affirmatively to above two mentioned questions were classified as surgical failure.

All the patients received either general or continuous epidural anesthesia, with the body in a modified dorsal lithotomy position. The TVT-O procedure was performed at the end of the surgery. Patients received either of the two pelvic reconstructive repair kits. The Prosima system includes precut macroporous polypropylene mesh implants, a VSD, inserters, and a syringe. The mesh was placed according the manufacturer's instructions. Briefly, a channel was made between the vaginal epithelium and underlying prevesical tissue by hydrodissection after a full thickness incision on the vaginal epithelium. Then extend the channel until the bilateral ischial spines. The mesh was placed flat in vesicovaginal plane with arms rested through established channels and contacted the parietal fascia of the obturator internus muscle. At the completion of surgery, the VSD was placed in the vaginal lumen and sutured in place to prevent dislodgement [8,9]. The final VSD size and volume was decided by the surgeons. The VSD was retained at least three weeks after the surgery. Different from Prosima system, the Avaulta system lacked the VSD, but had a trocar-guided obturator mesh. In short, the dissection of the vaginal epithelium and bladder was performed forward into the vesicovaginal space till the ischial spines and tendinous arc of the levator ani muscle. According to the guideline of the product, the

mesh was positioned with the usage of four needle passages through the obturator foramen. Before the surgery, all patients received preoperative intravenous antibiotics either prophylactically or for curing urinary infection.

SPSS 13.0 (SPSS Inc., Chicago, IL, USA) statistics software was used to analyze all the data. Paired or independent t test for continuous normal variables, Wilcoxon signed rank test for continuous non-parametric variables, and Pearson chi-square, Continuity correction chi-square or Fisher's exact test for categorical variables. A difference was considered statistically significant when  $P<0.05$  for data.

## Results

### Population

A total of 57 women who presented with anterior vaginal wall prolapse (Table 1) and concomitant SUI were involved in this study, with 29 and 28 patients underwent Prosima mesh and Avaulta mesh kits, respectively. TVT-O was applied to correct the concomitant SUI at the end of the surgery. By multichannel Urodynamics examination preoperatively, there were 3 women displayed weak detrusor contractility (1 of Prosima group and 2 of Avaulta group,  $P=0.96$ ), the rest were normal. In addition, none of the women had bladder outlet obstruction or family history related to POP or SUI.

The basic patient demographics are detailed in Table 1. Groups were homogenous for age, BMI, parity, pregnancy, history, menopause and chronic diseases, such as hypertension and diabetes. The difference of preoperative anatomic characteristics, such as anterior vaginal wall prolapse POP-Q stage, was not significant

Table 1: Demographic and preoperative characteristics

Variables	Prosima (n=29)	Avaulta (n=28)	P value
Age, mean (SD), year	53.2 (7.6)	52.9 (7.3)	0.89 <sup>*</sup>
BMI, mean (SD), kg/m <sup>2</sup>	25.2 (2.0)	25.4 (2.0)	0.69 <sup>*</sup>
Parity, mean (SD), n	2.1 (1.3)	2.4 (1.0)	0.20 <sup>t</sup>
Pregnancy, mean (SD), n	3.7 (1.9)	3.7 (1.7)	0.97 <sup>t</sup>
Menopause, n (%)	14 (48.3)	12 (43.9)	0.68 <sup>‡</sup>
MUI, n (%)	3 (10.3)	5 (17.9)	0.66 <sup>t</sup>
UTI, n (%)	3 (10.3)	6 (21.4)	0.43 <sup>§</sup>
History, mean (SD), year	4.7 (4.9)	7.6 (8.2)	0.15 <sup>t</sup>
MUCP, mean (SD), cmH <sub>2</sub> O	47.1 (25.4)	50.4 (28.2)	0.26 <sup>t</sup>
ALPP, mean (SD), cmH <sub>2</sub> O	96.4 (24.8)	94.7 (17.6)	0.88 <sup>t</sup>
Operation history <sup>#</sup> , n (%)	8 (27.6)	5 (17.9)	0.38 <sup>‡</sup>
Hypertension, n (%)	1 (3.4)	4 (14.3)	0.33 <sup>§</sup>
Diabetes, n (%)	1 (3.4)	2 (7.1)	0.96 <sup>§</sup>

BMI: Body Mass Index, MUI: Mixed Urinary Incontinence, UTI: Urinary Tract Infection, MUCP: Maximum Urethral Closure Pressure, ALPP: Abdominal Leak Point Pressure

<sup>\*</sup>Operation history Included hysterectomy, oophorectomy, myomectomy, tubal ligation, uterine cystectomy and anti-incontinence surgery

<sup>t</sup>Independent t test

<sup>‡</sup>Wilcoxon signed rank test

<sup>‡</sup>Pearson chi-square test

<sup>§</sup>Continuity correction chi-square test

Table 2: Intraoperative and postoperative characteristics and perioperative outcomes

Variables	Prosima (n=29)	Avaulta (n=28)	P value
Operating time, mean (SD), min	110.5 (31.1)	116.1 (23.6)	0.24 <sup>*</sup>
Estimated blood loss, mean (SD), mL	92.9 (39.4)	83.9 (54.4)	0.12 <sup>*</sup>
Postoperative hospital stay, mean (SD), day	6.3 (3.5)	6.6 (3.1)	0.55 <sup>*</sup>
Postoperative Indwelling catheter duration, mean (SD), day	4.6 (2.0)	5.2 (3.1)	0.62 <sup>*</sup>
Outcomes			
Success (1 month), n (%)	28 (96.6%)	26 (92.9%)	0.53 <sup>t</sup>
Success (2 years), n (%)	27 (3.4%)	26 (92.9%)	0.97 <sup>t</sup>

<sup>\*</sup>Wilcoxon signed rank test

<sup>t</sup>Pearson chi-square test

**Table 3:** Subjective outcomes of the two operations preoperatively and 2 years postoperatively

Variables	Prosima (n=29)		Avaulta (n=28)	
	Preoperative	2 years	Preoperative	2 years
PFDI-20	99.0 (29.7)	34.2 (32.5)*	103.1 (41.3)	36.9 (34.5)*
POPDI-6	37.5 (15.3)	13.4 (14.2)*	40.0 (15.1)	13.7 (13.9)*
CRADI-8	32.9 (10.0)	4.7 (3.6)*	30.1 (13.4)	5.4 (4.4)*
UDI-6	28.6 (16.3)	16.1 (15.8)*	32.9 (20.2)	17.9 (17.2)*
PFIQ-7	54.8 (18.7)	15.9 (24.7)*	50.3 (26.1)	16.5 (22.5)*
POPIQ-7	14.6 (8.9)	3.0 (8.6)*	13.6 (9.3)	2.9 (7.0)*
CRAIQ-7	12.3 (5.8)	3.3 (5.8)*	10.5 (9.4)	3.4 (5.3)*
UIQ-7	20.2 (10.2)	9.7 (11.3)*	20.4 (11.0)	10.2 (11.4)*
PISQ-12*	30.8 (4.4)	35.4 (6.6)*	30.5 (4.6)	35.7 (5.8)*

PFDI-20: Pelvic Floor Distress Inventory short form-20, POPDI-6: Pelvic Organ Prolapse Distress Inventory-6, CRADI-8: Colorectal-Anal Distress Inventory-8, UDI-6: Urogenital Distress Inventory-6, PFIQ-7: Pelvic Floor Impact Questionnaire short form-7, POPIQ-7: Pelvic Organ Prolapse Impact Questionnaire-7, CRAIQ-7: Colorectal-Anal Impact Questionnaire-7, UIQ-7: Urinary Impact Questionnaire-7, PISQ-12: Prolapse/Urinary Incontinence Sexual Questionnaire short form-12

PFDI-20 and PFIQ-7 scores ranged from 0 (best score) to 300 (worst score), subscales scores ranged from 0 (best score) to 100 (worst score). PISQ-12 scores ranged from 0 (worst score) to 48 (best score). PISQ-12\* was only collected for patients who were sexually active (n=34).

Data presented as mean (SD).

\*P<0.05 compared to baseline by paired t test.

**Table 4:** Complications of the two procedures

Variables	Prosima (n=29)	Avaulta (n=28)	P value
Chronic pain	1 (3.4%)	3 (10.7%)	0.39*
Implant exposure	4 (13.8%)	1 (3.6%)	0.37*
urethral caruncle	1 (3.4%)	1 (3.6%)	1.00*

All the data are shown by number and percentage

Chronic pain included intermittent pelvic pain or vaginal pain

Implant exposure included mesh or sling exposure

\*Continuity Correction Chi-Square test

between the two groups ( $P>0.05$ ). The distribution of mixed urinary incontinence (patients complained simultaneous urgency) and urinary tract infection (urine white blood cells were positive) was 3, 5 in Prosima group and 3, 6 in Avaulta group, respectively (all  $P>0.05$ ). The patients did not undergo either of the procedures until urine routine was negative by treatment with intravenous antibiotics. Of the 57 patients, 8 and 5 from Prosima and Avaulta group had a history of pelvic surgery of which the purpose was not for POP repair.

### Perioperative characteristics and objective results

The perioperative data are summarized in Table 2. It is worth mentioning that the operating time data extracted from medical records were the whole course of anesthesia, more than the time cost by TTVT-O plus POP repair. What's more, the difference of operating time between the two groups implied no significant statistics. Similarly, estimated blood loss, postoperative hospital stay and postoperative indwelling catheter duration were not different significantly of the two groups. According to the criterion described above, the anatomic success rates at 1 month of Prosima and Avaulta groups were 96.6% (28 of 29 patients) and 92.9% (26 of 28 patients) ( $P>0.05$ ). This indicated that the two mesh kits had similar success ratios of our research. While at 2 years, POP recurred in 1 woman of Prosima group and no recurrence of Avaulta group in present study, and the difference was not significant statistically ( $P>0.05$ ).

One failure case of Prosima group occurred at 1 week postoperatively as anterior vaginal wall prolapse relapsed which can be seen outside, and the situation was ongoing to be worse in 6 months when the prolapse organ swelled in a table tennis-like bulk (POP-Q stage IV). One woman in Avaulta group failed for uncured POP, and the other failure case happened to be not managed SUI, which were exacerbated than previous. One suffered from vesical perforation by reason of local tissue synechia.

### Subjective outcomes

The baseline subjective information before the operation was extracted from medical records. Besides, we got an elaborate subjective assessment from the patients after the operation at 2 years. The scores of 3 validated questionnaires, which including PFQI-20, PFIQ-7 and PISQ-12, were reported in Table 3, each scale of the 3 instruments was statistically significant improvement from baseline ( $P<0.05$ ) and no difference was detected between groups no matter at baseline or 2 years. Among the 34 sexually active women, with 17 in either group, 6 in Prosima group and 8 in Avaulta group resumed sexual activity by 6 months following the operation, all these women reported statistically significant improvement compared to preoperation ( $P<0.05$ ). But no difference was observed between groups ( $P>0.05$ ). In addition, either group had 2 women lost sexual activity due to personal or partner-related reasons.

### Complications

Chronic pain included chronic pelvic and vaginal pain in our study was detected in 1 patients of Prosima group and 3 of Avaulta group, respectively. The Avaulta kits were more likely to cause chronic pain, the difference was not statistically significant ( $P>0.05$ ). The rate of implant exposure (included mesh or sling exposure) of Prosima group was higher than that of Avaulta group, but indicated no difference statistically. Either group had 1 person developed urethral caruncle at the vaginal incision (Table 4). No de novo dyspareunia, mesh or sling erosion was detected during the follow-up period.

### Discussion

The mainstay therapy for symptomatic POP is surgery [16]. Our present study was designed to evaluate outcomes of two different meshes for treatment of anterior vaginal wall prolapse with a concomitant midurethral sling for SUI. Though we were unable to realize the patients' specific anatomic status at 1 or 2 year for its retrospective feature, whatever we knew was whether the anatomy conformed to the success criterion. However, it has been proved that women with prolapse beyond the hymen were more probable to represent pelvic floor symptoms and report a vaginal bulge than those with prolapse at or below the hymen [17,18]. In addition, the absence of vaginal bulge had the closest association with patients' assessment of global improvement and alleviation of symptom bother and quality of life, while anatomic alone did not [2]. Based on those, we also indirectly evaluated anatomic outcomes annually by two simple questions picked out from PFQI-20 questionnaire at 1 month and 1 year to inspect surgical success. Compared the 3 questionnaires of baseline with 2 years postoperatively, the anatomically cured patients reported qualitative improvement significantly in subjective assessment.

It is generally acknowledged that the outcomes of same repair procedures from different studies are often difficult to compare owing to variations in patient population, surgical technique, indication for repair, and even definitions of success. Besides, the outcomes may be confounded by concomitant surgeries, such as repair in other compartments and MUS [2,19]. Whereas, to resolve these challenges, we made an attempt to compare two different synthetic meshes in the same study. In this research, all women underwent single mesh accompanied by TTVT-O. Furthermore, we used the same definition of success and the same questionnaires to evaluate the results of the two repairs. However, we found the perioperative outcomes of two procedures were comparative in our research.

Generally, vaginal mesh kits were used to strengthen the anterior vaginal wall, and restore pelvic anatomy. The advantages of Prosima kit comprised smaller dissection area and avoidance of blind puncture, consequently less hemorrhagia, skin infection and less postoperative pain. In a multicenter series of 130 women who received this surgery and attended a 1 year visit, Zyczynski et al. [20] observed overall objective anatomic success (POP-Q stage 0/I) was 76.9% at 12 months and shortened wear of VSD (retained for

<21 days) was associated with a higher failure rate. However, our study was not powered to ascertain this effect attributed to VSD. By contrast, Avaulta kit was more operator friendly by using a guided trocar for insertion the mesh, and 4 skin incisions were required in the groin region [10]. Culligan and colleagues [21] employed the device achieved a 78% surgical cure rate at about 1 year for their anterior compartment prolapse group by an analogous evaluation criterion.

The success rates of POP or SUI were high and not different significantly between groups which might result from inadequate sample size or follow-up period. Interestingly, patients in China worried so much about their conditions that they rested excessively, which more or less contributed to low occurrence rate. Apart from that, chronic pain and mesh exposure were also popular long-term complications. As was expected, Avaulta procedure yielded more pain than Prosima possibly for its more skin incisions. However, no de novo dyspareunia, mesh or sling erosion was reported in our study though they frequently occurred in others' [7,10].

Notably, the two meshes improved anatomical and functional outcomes compared to baseline, with a low rate of complications in our study. But we almost did not conclude a statistical difference of any part between the two groups, which might be due to its retrospective feature and a smaller population. Moreover, we did not compare the outcomes among different POP-Q stages. Even so, it could not mean such a difference really did not exist. In addition, both the two devices were expensive to patients from a developing country like China. Each of these devices cost approximately ¥12,000 - ¥14,000. This may be helpful to curtail sample size as quite a few women could not afford to these kits. Hereby, more prospective, large size and long term observational studies should be taken in future to resolve the limitations in our research.

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