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# A BLOOD SUPPLY PRESERVING VAGINAL WALL DISSECTION TECHNIQUE IN TRANSVAGINAL PLACEMENT OF POLYPROPYLENE MESH: LONG-TERM FOLLOW-UP

#### Hypothesis / aims of study

The Gynecare Prolift system (Ethicon, Somerville, NJ, USA) had been described as a safe and effective surgical device for the treatment of patients with Pelvic Organ Prolapse (POP) by cadaveric studies and peer-reviewed publications. Since the FDA issued the warning about Transvaginal Placement of Surgical Mesh (TVM) products for POP twice, negative opinions erupted against the use of vaginal mesh delivery systems. Last year, the Prolift and Prosima system products were withdrawn from the market but based on our data and experience, the confidence of these trocar-guided mesh delivery systems can still be assured.

The blood supply preserving vaginal wall dissection technique assumed that it can effectively avoid vaginal mesh exposure ("erosion") and keep vaginal wall as soft as it was before the preoperation. Preserving the vaginal wall blood supply is the key to a successful TVM. To assess the application of this technique, We evaluated the postoperative anatomic outcomes and complications in women undergoing anterior, posterior, and/or apical prolapse repair in our institution.

### Study design, materials and methods

Adult female patients with no desire of fertility who had suffered recurrent prolapse or grade 2 to 4 POP were eligible using the Pelvic Organ Prolapse Qualification (POP-Q) system. Those who had hysterectomy or supracervical hysterectomy due to benign etiology before our management were included as well into our sample of study. The recurrences of POP after hysterectomy or traditional non-mesh repair were also included in this study if they needed surgical intervention. Patients who had only traditional non-mesh repairs were excluded from the study. When patients with POP visited our urogynecology outpatient service, the basic information, symptoms and physical examination had been carefully taken. An evidence-based consultation was held to consider whether the benefits of mesh repair outweighed the risks. The Prolift polypropylene mesh was chosen for most of patients. The Prosima was chosen in small part due to the slight symptoms and low Body Mass Index (BMI). All meshes were implanted properly as their design.

The blood supply preserving vaginal wall dissection technique was based on anatomical details and intended to separate the fully thickness vaginal wall. To protect the blood supply for the whole vaginal tissue, electrocoagulation was never used. When performing anterior prolapse repair, 40-ml normal saline (without epinephrine) was injected to the vesicovaginal septum from the middle of vaginal wall towards left and right side. As long as the syringe in the correct layer, the vaginal wall only became swollen but not pale. Taking vertical incision in the vaginal wall by a certain depth, the white visceral pelvic fascia could be seen clearly on the artificial water sac since hydrodissection. The amount of bleeding was minimized during the process of sharp separation. After dissecting accurately, the blood supply network would be observed inside vaginal wall through the white visceral pelvic fascia. Performing posterior prolapse repair was similar, merely changing injection target to the rectovaginal septum. The main space under the entire vaginal wall must be well separated so that the body of mesh could be fully spread. Meanwhile, the body of mesh could be shaped according to the main space. On the contrary, the space for the arms did not require fully separation, only needs to explore to the key region of anatomy with forefinger. The obturator foramen and ischial spine could be identified anteriorly, and the sacrospinous ligament posteriorly.

All patients were required a subsequent visit 3 months postopretively. At that time, the objective anatomical outcomes (POP-Q) and subjective complaint were carefully taking. After that, we sent text message to the patients occasionally to observe if there was any complication including LUTS, incontinence, pain and mesh exposure. They were glad to visit our urogynecology outpatient service again to accomplish the follow-up after receiving message. This process becomes routine, but our study ended in late 2012.

#### Results

A total of 175 consecutive women (age range 34 to 86) with pelvic organ prolapse underwent TVM were enrolled retrospectively in this study from the year of 2008 to 2012 in our institution (Table 1). There were 24 (22 Prolift "T", 2 Prolift "A") cases of hysterectomy due to benign aetiology, 4 (Prolift "T") cases of recurrent prolapse after vaginal hysterectomy, and 7 (2 Prolift "T", 3 Prolift "A", 1 Prolift "P" and 1 Prosima "C") cases of recurrent prolapse after non-mesh repair. All patients completed the follow-up in the third months. After that, the cases of withdrawal rised gradually. By now, the follow-up rate is 81%. Months from surgery to last clinic visit (median, longest and shortest) were 17, 51 and 3 for all patients.

The blood supply preserving vaginal wall dissection technique was applied to each case by one female urologist. The operative time of dissection (anterior or posterior) was less than 10-min. There were no bladder injury or rectum injury occurred due to dissection. Bladder injury occurred in 1 Prolift "A" patient and 1 Prolift "T" patient by trocar passing of anterior distal arm.

The anatomic outcomes are displayed in table 2. Each point preoperative and postoperative was compared using paired samples t test. All P values were less than 0.001. During our long-term follow-up, there were no vaginal mesh exposure and pelvic pain occurred. One recurrence prolapse occurred 6 months after our procedure (Prosima "C"). Twenty-four female (mean age 50±5 years) were sexually active postoperative with better quality. Nearly all patients expressed extreme satisfaction with our urogynecology management.

## Interpretation of results

Vaginal anatomical reconstruction with no mesh exposure was achieved by TVM, which kept full vaginal length, width and thickness, restored vaginal functional shape. The fundamental cause of mesh exposure is vaginal wall necrosis. Vaginal wall necrosis is due to the damage of blood supply. Thus, in order to make sure no mesh exposure, the blood supply for the vaginal wall must be carefully protected.

Injection with epinephrine will make blood vessel contract. The injection applied in the vaginal wall (become pale) could minimize the bleeding during the separating process. But low amount of bleeding does not mean that the integrity of blood supply for the vaginal wall is preserved during separation. Contrarily, it also could be the outcome of vague anatomic phase and its destruction on blood supply. There won't be much amount of bleeding, if the technique is properly practiced. The bleeding won't need treatment like electrocoagulation or suture. The absence of complicated treatment also helps protect the blood supply.

The mesh must be appropriately shaped. That makes the body of the mesh can be fully spread in the main space avoiding its fold and twist. Such practices will help the surgeons avoid mesh misplacement and then preventing vaginal wall from losing its elasticity.

### Concluding message

Blood supply preserving vaginal wall dissection technique is reproducible and normalizable. TVM performed by experienced surgeon do not expose patients to higher risk. Some unexpected and unsatisfied outcomes occurred due to the law of surgical learning curve. Consequently, some opposing opinions against these newly invented practices emerged. To better understand this approach, more detailed communication of surgical technique is required. As technologies progress, advanced mesh products will become dominated treatment of POP.

Table 1 patients' information

	Prolift "A"	Prolift "P"	Prolift "T"	Prosima "A"	Prosima "C"
n	37	4	113	3	18
Age, mean ±SD	59±13	52 (median)	67±11	56 (median)	64±9
BMI, mean ±SD	24.9±5.1			22.5±2.7	
Concurrent midurethral sling	19	0	6	1	2

Table 2 anatomic outcomes using POP-Q system

POP-Q	Prolift "A"	Prolift "T"	Prosima "C"
Aa, mean ±SD (pre-, post-)	0.4±1.2, -2.6±0.5	1.1±1.4, -2.0±0.8	0.4±1.1, -2.4±0.5
Ba, mean ±SD (pre-, post-)	1.2±1.3, -2.6±0.5	2.6±1.8, -2.0±0.8	1.6±1.1, -2.4±0.5
C, mean ±SD (pre-, post-)	-0.7±1.4, -5.7±1.1	2.2±2.5, -5.9±1.2	0.8±2.1, -6.3±1.4
Ap, mean ±SD (pre-, post-)	-1.8±0.7, -2.5±0.5	0.5±1.5, -2.4±0.5	-0.4±1.5, -2.5±0.4
Bp, mean ±SD (pre-, post-)	-1.7±0.9, -2.5±0.5	0.9±2.2, -2.4±0.5	-0.2±1.6, -2.5±0.4

#### Disclosures

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