Original Article

Laparoscopic-Assisted Tension-free Vaginal Mesh: An Innovative Approach to Placing Synthetic Mesh Transvaginally for Surgical Correction of Pelvic Organ Prolapse

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Polypropylene mesh implants for the correction of pelvic organ prolapse (POP) are now available in Japan. We developed an innovative approach for correcting POP by placing polypropylene mesh transvaginally with laparoscopic assistance. From June 2007 through March 2010, sixteen consecutive patients with symptomatic stage 2 or 3 pelvic organ prolapse underwent the laparoscopic-assisted tension-free vaginal mesh procedure at Okayama University Hospital. All patients were evaluated before and at 1, 3, 6, and 12 months after surgery. Female sexual function was also evaluated with the Female Sexual Function Index (FSFI). The procedure was performed successfully without significant complications. Fifteen of 16 patients were considered anatomically cured (93.8%) at 12 months postoperatively. One patient with a recurrent stage 3 vaginal vault prolapse required sacral colpopexy six months postoperatively. Total FSFI scores improved significantly from 10.3 ± 1.3 at baseline to 18.0 ± 1.2 at 12 months after surgery. The laparoscopic-assisted trans-vaginal mesh is a safe, effective, and simple procedure for POP repairs. The procedure not only restores anatomic relationships but also improves sexual function.

Key words: tension-free vaginal mesh, pelvic organ prolapse, laparoscopic, female urology, sexual function

P elvic organ prolapse (POP) affects a significant number of postmenopausal women. An American woman has an estimated 11.1% lifetime risk of undergoing a single operation for POP or urinary incontinence by the age of 80 years [1]. The first line of treatment is often surgical repair. The tension-free vaginal mesh (TVM) procedure [2] for pelvic floor reconstruction is gaining favor due to its minimally invasive vaginal approach, low morbidity, option for uterine preservation, and applicability to most types of POP. Results from a recent 3-year prospective follow-up study of this procedure are comparable to traditional repair procedures [3].

In Japan, transvaginal hysterectomy and colpoplasty are commonly performed for POP. Although the TVM technique has been practiced in Japan since 2005, surgical kits such as the Prolift® (Gynecare) have yet to receive governmental approval in Japan. Therefore, the procedure is commonly performed by cutting polypropylene mesh, which is available in

Japan, into a shape that approximates the shape of the mesh found in the kit.

Recent advances in surgical techniques, including development of the TVM procedure, have renewed interest in the surgical treatment of POP. Challenges of the TVM technique include restricted visibility and mobility within the operative field and the complexity of the pelvic floor anatomy. We developed an innovative approach for placing polypropylene mesh transvaginally in which laparoscopy facilitated the procedure.

Materials and Methods

Patients and preoperative measures. We developed an original surgical technique employing the tension-free application of polypropylene mesh with laparoscopic assistance for the correction of defects of the anterior vaginal wall (laparoscopic-assisted TVM). POP was characterized and evaluated according to the International Continence Society pelvic organ quantification (POPQ) staging system [4]. From June 2007 through March 2010, sixteen consecutive patients with symptomatic stage 2 or 3 POP underwent laparoscopic-assisted TVM at Okayama University Hospital. Eight patients with cystoceles underwent an anterior repair, and eight patients with prolapse of the apical compartment underwent both anterior and posterior repair. Surgery was considered only when conservative treatment failed or patients explicitly requested it. Conventional urodynamic studies, including uroflowmetry with residual urine measurement, filling cystometry, pressure flow study, and abdominal leak point pressure were undertaken for all patients preoperatively. The methods, definitions, and units we used conformed to the standards recommended by the International Continence Society.

Surgical procedure. The first half of the procedure was laparoscopic and occurred with the patient in a low lithotomy position. The transvaginal approach with the patient in high lithotomy was used during the second half of the surgery. Two surgeons performed the transvaginal portion and 2 the laparoscopic portion. The operating surgeon of the laparoscopy team stood to the patient's left, and the assistant stood to the patient's right. The monitor was placed caudal to the patient. The surgeon (as well as the assistant) of the TVM team stood between the patient's legs. The TVM team also utilized laparoscopic information, so a second video monitor was placed to the right of the patient's head (*i.e.,* behind the assistant of the laparoscopy team) (Fig. 1A).
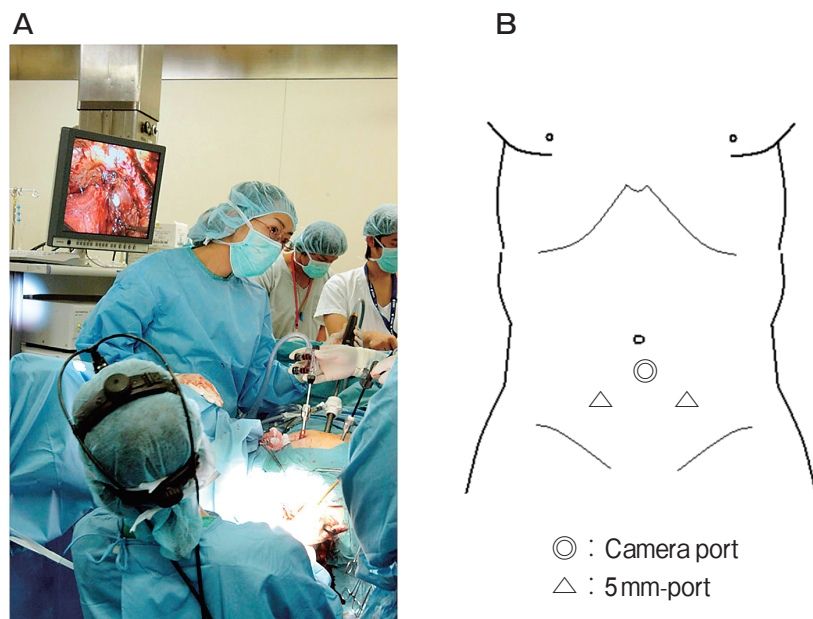

Fig. 1   **A**, Overview of the operation field; **B**, Schema of trocar introduction and incision.

◎：Camera port
△：5mm-port

1. Laparoscopic approach

We used a 3-port extraperitoneal laparoscopic technique involving one 10-mm umbilical trocar and two 5-mm suprapubic trocars (Fig. 1B). After entering the retropubic space, we used blunt dissection to visualize the vaginal wall and endopelvic fascia on each side of the urethra (Fig. 2A). The important anatomic landmarks were the symphysis pubis, the urethra, and the bladder base in the midline, the obturator neurovascular bundles, Cooper's ligaments, the ischial spine, and the arcus tendineus fascia pelvis (ATFP). The ischial spine was easily identified laparoscopically with forceps.

2. Transvaginal approach

The TVM surgical technique was described previously [2, 5]. Briefly, a macroporous, monofilament polypropylene mesh (Gynemesh PS; Ethicon, Somerville, NJ, USA; $25 \times 25\,cm$) is cut into a similar shape as that used in the Prolift system (Ethicon; Somerville, NJ, USA). Cystocele correction entails the bilateral trans-obturator passage of the mesh to suspend it. Custom-made angled, eyed needles with two different angles are used to pass nylon loops through the obturator foramen, and then the mesh arms (four in the anterior vaginal wall) are placed using the nylon loops. On either side, both arms of the mesh are passed into the paravesical region using custom-made needles. The anterior, sub-vesical strap is inserted into the ATFP approximately 7 mm from the posterior surface of the pubis, and the posterior, sub-vesical strap is inserted into the ATFP 10 mm from the ischial spine with laparoscopic assistance (Fig. 2B, C). If the ischial spine cannot be identified laparoscopically, then it must be identified vaginally prior to proceeding. The laparoscopic surgeon guides the fingers of the surgeon on the vaginal side with forceps. Bipolar forceps are used for hemostasis, if necessary. The mesh is pre-cut and then adjusted
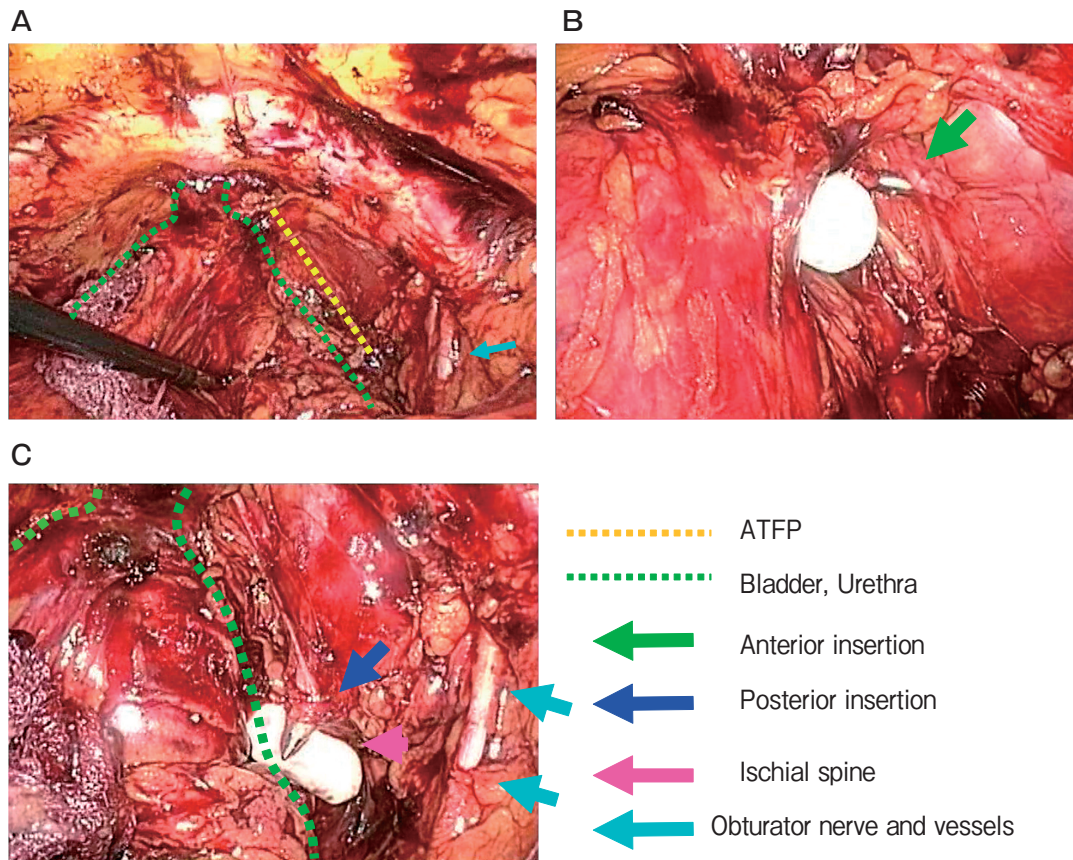
Fig. 2   A, The exposed space of Retzius; B, The anterior, subvesical strap is inserted in the ATFP approximately 7 mm from the posterior surface of the pubis; C, The posterior, subvesical strap is inserted in the ATFP 10 mm from the ischial spine.

according to the type of correction required. Traction over the exteriorized arms of the sling ensures correct positioning. After cystoscopy, the colpotomy is closed with a 2–0 Vicryl running suture without an additional colpectomy. No drain is placed, and the laparoscopic port incisions are closed. Finally, a vaginal compress is inserted for 24 h. Menopausal patients receive perioperative topical estrogen treatment for 3 months.

Outcome measures. Treatment efficacy and complications of each patient were systematically assessed at 1, 3, 6, and 12 months after surgery. In the majority of cases, postoperative evaluations were performed by the operating surgeon. With regard to anatomical outcome, postoperative POP-Q stage 2 or more of any operated vaginal compartment was considered a surgical failure.

Female sexual function was evaluated with the Female Sexual Function Index (FSFI) [6] before and 6 months after surgery. The FSFI is a validated and reliable measure of female sexual function. It has 19 questions that assess 6 domains of sexual function, including desire, arousal, lubrication, orgasm, satisfaction, and pain. The composite score is determined by the sum of the domains multiplied by the domain factor. The full-scale score range is from 2 to 36, with higher scores associated with a lesser degree of sexual dysfunction. Patients who underwent laparoscopic-assisted TVM surgery answered the FSFI preoperatively and at 6 and 12 months postoperatively. Baseline patient characteristics, demographic data, and sexual activity were also collected. The study was approved by the ethics committees of Okayama University hospital.

Statistical analysis. Values are reported as the means plus or minus the standard deviation. Statistical analysis was performed using the Wilcoxon signed-rank test, with p values of less than 0.05 considered statistically significant. The Statistical Package for Social Sciences for Windows version 12.0 (SPSS, Chicago, IL, USA) was used for the statistical analysis.

Results

The mean age of the 16 patients ($\pm$ SD) was 65.2 $\pm$ 9.0 years old (range 47–80). The mean weight was 56.5 $\pm$ 7.2 kg (range 45.8–67.0), and the mean parity was 2.2 $\pm$ 0.4 (range 2–3). There were 4 patients who had undergone a previous hysterectomy, one had a previous surgery for prolapse, and no patients were previously operated on for stress urinary incontinence.

Table 1 shows surgical characteristics and perioperative complications. The mean operative time was 138 $\pm$ 15 minutes for patients who underwent only an anterior repair and 145 $\pm$ 27 min for those who underwent both anterior and posterior repairs. We experienced one bladder injury and no rectal injuries. Of the 16 patients, 3 had stage 2 anterior vaginal wall prolapse (18.8%) and 13 had stage 3 (81.2%) on preoperative pelvic examinations according to the POP-Q staging system. At follow-up, 15 of 16 patients were considered anatomically cured (93.8%) at 12 months after surgery. One patient with a recurrent stage 3 vaginal vault prolapse required sacral colpopexy six months after the first surgery.

Blood loss was less than 25 ml for all laparoscopic cases except for one patient with 210 ml blood loss. In this case, the bleeding point was laparoscopically identified, and hemostasis was achieved using bipolar forceps via a laparoscopic approach. Blood transfusion was not required in this case. Bladder injury was recorded in one patient. The bladder injury occurred during the dissection of the paravesical space by the surgeon of the TVM team. One woman without stress urinary incontinence (SUI) before surgery who underwent laparoscopic-assisted TVM-A developed SUI. SUI had not been seen on the preoperative urodynamic study. This patient required a mid-urethral sling by a trans-obturator approach. One patient (6.3%) developed small mesh erosion at the anterior vaginal wall, which was successfully treated with a simple excision of mesh and vaginal hormonal therapy.

Total FSFI scores improved significantly from

Table 1 Surgical characteristics and perioperative complications

	Anterior n = 8	Anterior + Posterior n = 8
Operation time (min)	138 $\pm$ 15	145 $\pm$ 27
No. of Complications		
Bladder injury	1	0
Blood loss over 200 ml	1	0
Vaginal erosion	0	1
Recurrence of POP	0	1

10.3 ± 1.3 at baseline to 15.5 ± 1.6 at 6 months ($p = 0.01$) and 18.0 ± 1.2 at 12 months after surgery ($p = 0.001$) (Fig. 3). The lowest domain score was noted in arousal, followed by orgasm, lubrication, desire, pain, and satisfaction (Table 2). Scores of all domains were improved. In particular, the arousal, lubrication, and orgasm domains improved significantly at 12 months postoperatively. Frequency of sexual activity also improved from 0.9 ± 0.4 per month at baseline to 1.8 ± 1.2 at 12 months after surgery.

Discussion

The wide variety of surgical approaches used to treat POP is a reflection of the complexity of its management. All procedures require sound surgical

Wilcoxson signed-rank test

Fig. 3   Changes of FSFI score between before and after surgery.

judgment, a complete understanding of pelvic anatomy and the mechanisms involved in pelvic organ prolapse, and expertise in pelvic surgery [7]. The present study demonstrates that laparoscopic-assisted TVM can be performed with a relatively low rate of perioperative complications including bladder injury, blood loss, and mesh erosion, which was comparable to the results presented in a recent Japanese report describing the use of conventional TVM [8]. The overall anatomical cure rate was 93.8% at one year, which was comparable to the results of a recent, randomized, controlled trial (RCT) using non-standardized polypropylene mesh for the anterior repair [9] Jacquetin *et al.* reported 3-year clinical outcomes of the conventional TVM with an 80.0% anatomical cure rate [3]. The limitation of our study is that it was a small and preliminary study. Further prospective study is necessary to compare the laparoscopic-assisted TVM with a balanced and matched conventional TVM group.

Kato *et al.* [8] described the TVM techniques and have shown that this procedure has a low complication rate when performed by an experienced surgeon. While the minimally invasive surgical route is beneficial for older patients or those with medical comorbidities, portions of the procedure are performed blindly, increasing the risk of complications. Failure to fully understand pelvic anatomical relationships when placing the trocars can be catastrophic. Although the rate is low, hemorrhage can result from vascular injury. Additionally there are reports of patients requiring transfusion [10] and arterial embolization for hemostasis [11].

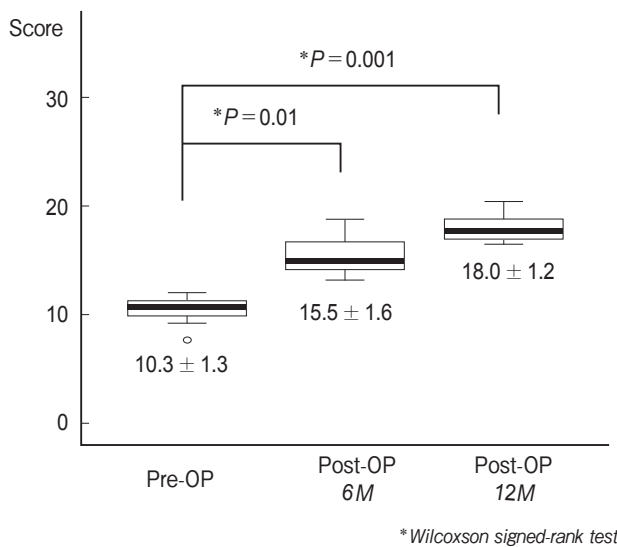In 2004, the Japanese Urological Association and the Japan Society of Endourology and ESWL estab-

Table 2   FSFI scores for each sexual function domain

No. of pt.	Pre-OP 16	Post-OP 6M 15	Post-OP 12M 14	p Value (Pre vs 12M)
Desire	1.8 ± 0.5	1.9 ± 0.2	2.0 ± 0.4	0.381
Arousal	1.0 ± 0.5	2.2 ± 0.6	3.2 ± 0.5	<0.001*
Lubrication	1.4 ± 0.7	3.0 ± 0.5	3.4 ± 0.5	<0.001*
Orgasm	1.3 ± 0.5	2.7 ± 0.6	3.4 ± 0.6	<0.001*
Satisfaction	2.8 ± 0.9	3.1 ± 0.6	3.2 ± 0.6	0.294
Pain	2.0 ± 0.8	2.6 ± 0.5	2.8 ± 0.6	0.08
Overall	10.3 ± 0.5	15.5 ± 1.6	18.0 ± 1.2	<0.001*

Wilcoxon signed-rank test

lished a certification system for urological laparo-
scopic surgery. Laparoscopic surgical techniques
should be mastered by a urologist, as such techniques
may facilitate vaginal procedures. Our laparoscopic-
assisted TVM procedure enables the complete visual-
ization of the needle inserted from the vaginal side.
This would theoretically prevent injuries to the blad-
der, vessels, and nerves caused by needle insertion.
In addition, the surgeon and assistant share the same
field of view, so reduction in complications can be
expected. As mentioned previously, in one patient, a
bleeding point at the venous plexus of the bladder neck
following dissection via the vagina was identified and
managed laparoscopically.

Success of the TVM procedure depends on the
deployment and fixation of the mesh. The procedure
entails the use of needles to pass the mesh legs
through to their proper locations. This portion of the
procedure is performed blindly [8]. Laparoscopy,
however, may be used to visualize the needles as they
are passed.

Evidence from prospective studies has demon-
strated that POP adversely affects sexual function
[12–14]; however, studies assessing sexual function
following surgical repair have presented conflicting
results. Several authors have documented improve-
ments in sexual function [15], whereas others noted
no change, or deterioration [16, 17]. The causes of
worsening sexual function after surgery may be
related to dyspareunia, reduced lubrication, and
reduced genital sensation [18]. The presence of a
foreign body such as polypropylene mesh may provoke
an inflammatory reaction in the highly innervated,
vascular anterior vaginal wall. This has been shown in
rat models that employ suture implantation to study the
inflammatory effects of foreign materials [19]. One
study reported that postoperative dyspareunia resulted
in deterioration of postoperative sexual function [20].
In our study, 1 (6.3%) patient complained of dyspare-
unia due to vaginal erosion. At 4 months, this patient
presented with complete epithelialization of the vagina
after the mesh was partially excised, and her pain
scores improved at 6 months postoperatively.

In conclusion, this is the first report describing the
outcomes for laparoscopic-assisted TVM. This proce-
dure is associated with satisfactory subjective and
objective outcomes, with limited adverse events. The
acceptance of a newly introduced surgical procedure

requires that its benefits outweigh its risks. Caution
is therefore advised until sufficient follow-up data
regarding QOL, sexual function, pelvic pain, the
long-term *in vivo* biocompatibility of polypropylene
mesh, and sustainability of the achieved anatomical
and functional results in comparison to conventional
techniques are available.

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