

Clitoral Blood Flow Changes after Surgery with Tension-Free Vaginal Mesh for Pelvic Organ Prolapse

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We measured basal clitoral blood flow by Doppler sonography to determine whether tension-free vaginal mesh (TVM) affects the clitoral blood flow and sexual function in women with pelvic organ prolapse (POP). We performed a prospective study of 22 patients who underwent TVM for POP. Clitoral blood flow was measured by Doppler ultrasound. The resistance index (RI), pulsatility index (PI), peak systolic velocity (PSV), and end-diastolic velocity (EDV) of the clitoral arteries were measured preoperatively and at 1, 3, and 6 months postoperatively. Female sexual function was also investigated with the Female Sexual Function Index (FSFI). The mean PI and RI were increased at 1 month and significantly decreased at 6 months postoperatively ($p < 0.05$). In contrast, the mean PSV and EDV decreased at 1 month postoperatively and increased at 6 months postoperatively. These four parameters recovered to baseline levels at 6 months following surgery. Total FSFI scores improved significantly from 10.2 ± 7.9 at baseline to 18.2 ± 8.9 at 6 months postoperatively. Color Doppler ultrasonography is potentially useful in measuring clitoral blood flow in patients treated with TVM for POP. Prospective long-term studies are needed to evaluate the utility of this modality as a diagnostic and prognostic tool for female sexual dysfunction.

Key words: clitoris, pelvic organ prolapse, Doppler ultrasound

Pelvic organ prolapse (POP) affects a significant number of women. An American woman has an estimated 11.1% lifetime risk of undergoing a single operation for pelvic organ prolapse or urinary incontinence before 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 a minimally invasive vaginal approach commonly used to repair POP. The morbidity of POP impacts a woman's social, physiological, occupational,

domestic, physical, and sexual well-being [3]. Of these, the effect of POP on a woman's sexual function has been poorly studied, with most efforts focusing on objective outcomes such as the efficacy of the operative technique and its possible complications.

Because most studies assessing sexual function depend on self-questionnaires, an objective, reproducible, and standard method is needed for studies in this area. The interpretation of vascular changes in the clitoris is one area of investigation, and clitoral blood flow measurement by color Doppler sonography is one way

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to assess female sexual response [4]. Little information is available about the influence of pelvic organ surgery on the clitoral circulation. We conducted the present study to measure the basal clitoral artery blood flow by Doppler sonography and to determine whether TVM has a significant effect on clitoral artery blood flow and sexual function in women with POP.

Patients and Methods

This prospective study was conducted at the Department of Urology, Okayama University Hospital, Okayama, Japan. The institutional ethical committee of the department approved the study. The study is registered at the Clinical Research Ethical Review Board of Okayama University Graduate School of Medicine under trial no. 865. All of the patients provided written informed consent before entering the study, which was conducted in accordance with the Declaration of Helsinki. The study was not advertised and no remuneration was offered.

Pelvic organ prolapse was characterized and evaluated based on the International Continence Society's Pelvic Organ Prolapse Quantification (POP-Q) staging system [5]. Thirty-nine consecutive women with POP stage 3 or 4 defined by the POP-Q staging system who were scheduled to undergo surgical correction using TVM were enrolled. None of the women were on hormone replacement within 1 year prior to or during the study period. Gynemesh PS[®] 25 × 25 cm polypropylene mesh (Ethicon, Somerville, NJ, USA) was used for the procedure. The mesh was cut into a shape similar to that found in the Prolift[®] (Ethicon) system with the use of a paper pattern [6]. Custom-made eyed needles with two different angles were used to pass nylon loops through the obturator foramen and sacrospinous ligament. The mesh arms (four in the anterior vaginal wall, and two in the posterior vaginal wall) were then pulled through using the nylon loops [7, 8].

Clitoral blood flow was measured by Doppler ultrasound preoperatively and at 1, 3 and 6 months postoperatively. Female sexual function was also investigated with the Female Sexual Function Index (FSFI), a 19-question self-report measure organized into six domains: desire, subjective arousal, lubrication, orgasm, satisfaction, and pain [9]. Each domain was scored on a scale of 0 or 1-6, with a higher score indicating better function. For each of the six domains, the

patient's score was calculated and the total score was obtained by adding the six domain scores. The total score range was 2-36. In this study, a validated Japanese version of the FSFI was used.

Doppler ultrasonography. Doppler ultrasonography was performed using a commercially available color Doppler scanner (Prosound α -7[®], Aloka, Tokyo) with a 12-MHz linear array transducer. All of the patients were scanned in the lithotomy position. The Doppler translabial probe was placed sagittally on the clitoris at an angle $<20^\circ$, without exerting any significant pressure on the genital tissues. After identifying the clitoral artery using color flow mapping, the probe was positioned over the vessel and at least three similar, sequential Doppler waveforms were obtained (Fig. 1). The peak systolic velocity (PSV), end-diastolic velocity (EDV), pulsatility index (PI) ($PI = PSV - EDV/V_{mean}$), and resistance index (RI) ($RI = PSV - EDV/PSV$) of the clitoral artery were calculated (Fig. 2). The total examination time for obtaining a satisfactory recording of the Doppler signals from the clitoral arteries was limited to approx. 1 min for each patient. All studies were performed by the same investigator.

Statistical analysis. Values are reported as the mean \pm standard deviation (SD). The statistical analyses were performed using the Mann Whitney *U*-test and the Wilcoxon signed-rank test, with *p*-values <0.05 considered significant. The Statistical Package for Social Sciences for Windows ver. 12.0 (SPSS, Chicago, IL, USA) was used for the statistical analyses.

Results

Of the 39 women who underwent a TVM procedure for POP, 22 were eligible for inclusion and the other 17 women were excluded because they were not sexually active. The mean age (\pm SD) was 65.8 ± 8.3 years old (range 48-80 years). The mean body mass index (BMI) of the 22 patients was 24.0 ± 2.3 (range 21-29), and their mean parity was 2.2 ± 0.4 (range 0-3). All 22 patients had stage 3 prolapse on preoperative pelvic examinations according to the POP-Q staging system. No patients were previously operated on for POP or stress urinary incontinence. We applied an anterior mesh in seven patients and a combined anterior and posterior mesh in 15 patients (Table 1).

The PI and RI reflect blood flow impedance, and the mean PI and RI of the 22 patients at baseline were

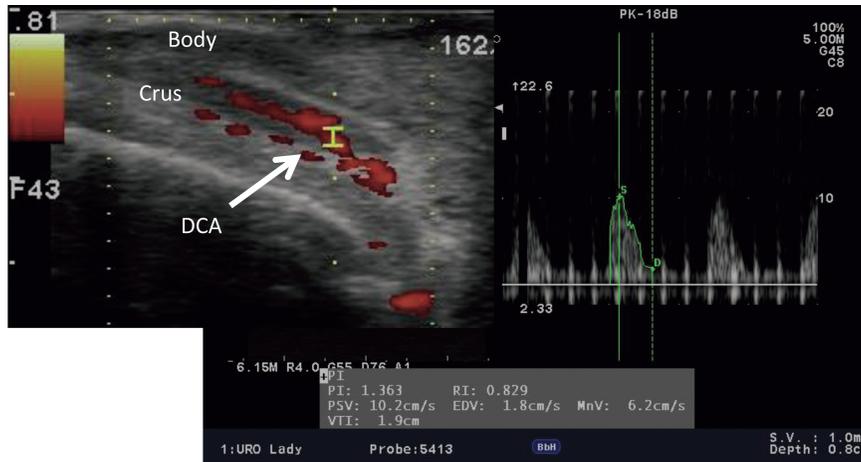
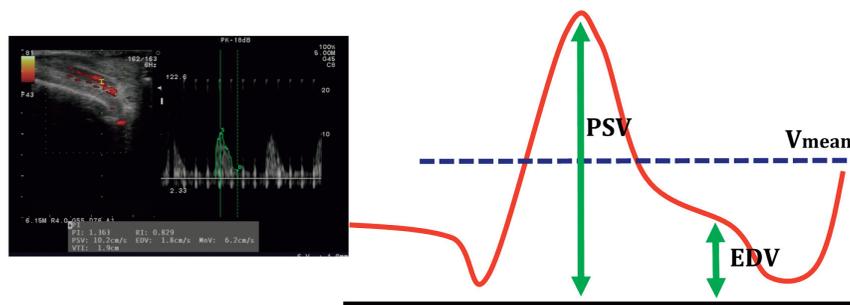


Fig. 1 Color flow images of the dorsal clitoral artery (DCA) using a color Doppler scanner (Prosound α -7[®], Aloka) with a 12-mHz linear array transducer. All patients were scanned in the lithotomy position. The Doppler translabial probe was placed sagittally on the clitoris at an angle $< 20^\circ$, without exerting any significant pressure on the genital tissues. After the clitoral artery was identified using color flow mapping, the probe was positioned over the vessel and at least three sequential Doppler waveforms were obtained.



- Peak systolic velocity (PSV)
- End-diastolic velocity (EDV)
- Pulsatility index (PI)= $\frac{PSV-EDV}{V_{mean}}$
- Resistance index (RI)= $\frac{PSV-EDV}{PSV}$

Fig. 2 The parameters of the color Doppler ultrasonography.

Table 1 Patient characteristics

| | |
|------------------------|------------------------|
| No. of pt. | 22 |
| Age (year) | 65.8 \pm 8.3 (48–80) |
| BMI | 24.0 \pm 2.3 |
| Parity (times) | 2.2 (0–3) |
| Menopausal | |
| Yes | 21 |
| No | 1 |
| Surgical procedure | |
| Anterior TVM | 7 |
| Anterior+Posterior TVM | 15 |

1.20 \pm 0.31 and 0.72 \pm 0.08, respectively. The PI and RI increased from 1.20 \pm 0.31 and 0.72 \pm 0.08 at baseline to 1.50 \pm 0.42 and 0.84 \pm 0.14 at 1 month after surgery, respectively. However, the mean PI and RI were significantly decreased at 6 months postoperatively compared to those at 1 month after surgery ($p < 0.05$) (Fig. 3). In contrast, the peak systolic velocity (PSV) and end-diastolic velocity (EDV) were 10.9 \pm 6.2 and 3.1 \pm 2.2, respectively. Both the PSV and EDV were decreased at 1 month after surgery, and then increased significantly at 6 months after surgery ($p < 0.05$) (Fig. 4). The patients' total FSFI scores improved significantly

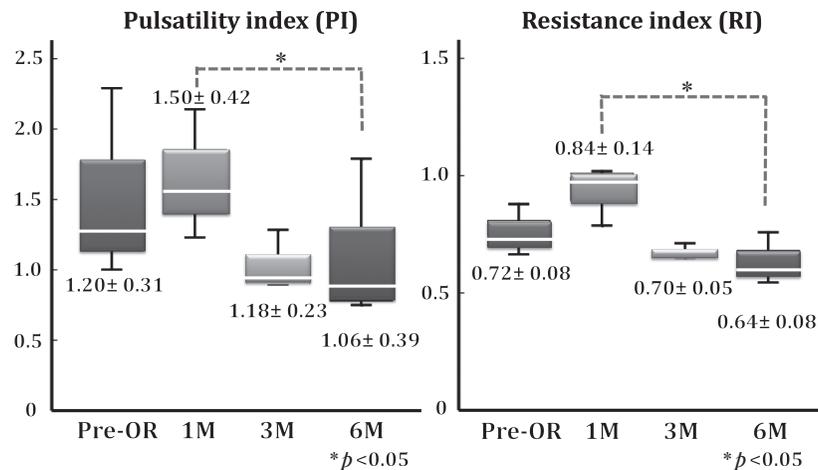


Fig. 3 Pulsatility index (PI) and resistance index (RI) pre-operatively and at 1, 3, and 6 months postoperatively. There were significant improvements in the PI and RI from 1 month to 6 months postoperatively. There were no significant differences in the PI or RI at 6 months postoperatively from baseline.

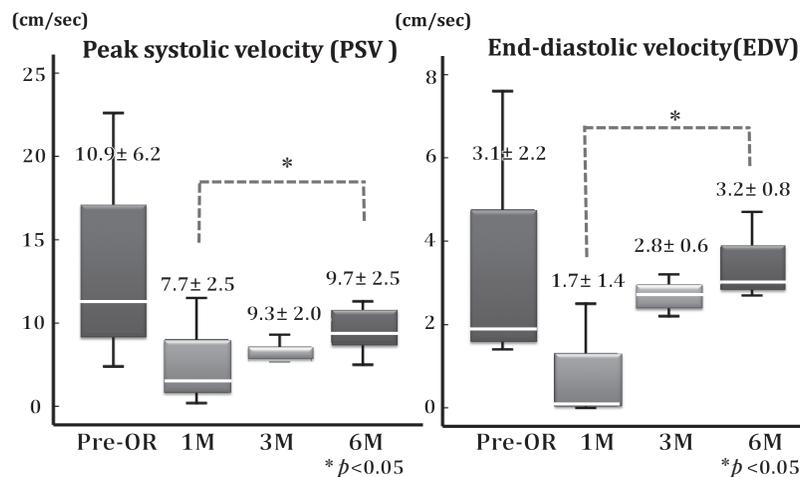


Fig. 4 Peak systolic velocity (PSV) and end-diastolic velocity (EDV) pre-operatively and at 1, 3 and 6 months postoperatively. There were significant improvements in PSV and EDV from 1 month to 6 months postoperatively. There were no significant differences between PSV and EDV at 6 months postoperatively from baseline.

from 10.2 ± 7.9 at baseline to 18.2 ± 8.9 at 6 months postoperatively ($p < 0.05$) (Fig. 5).

The sexual function scores for each of the six sexual function domains of the FSFI are shown in Table 2. The scores in all domains were increased postoperatively. In particular, the arousal, lubrication, and orgasm domains improved significantly at 6 months postoperatively. As the PI and RI decreased, the FSFI scores tended to increase and the FSFI scores also tended to increase as the flow velocity increased.

TVM was successful in all 22 patients, and no recurrence of prolapse or stress urinary incontinence

was observed at 6 months. There were no cases of vaginal mesh erosion at 6 months postoperatively. In all 22 patients, clitoral artery circulation was detectable by color Doppler sonography, and adequate flow velocity waveforms were obtained.

Discussion

As noted earlier, pelvic organ prolapse impacts a woman's social, physiological, occupational, domestic, and physical well-being, and POP may adversely affect sexual function [3,10-13]. Several studies assessing

sexual function following surgical repair have reported improvements in sexual function [14], whereas others noted no change, or deterioration [10, 14, 15].

The causes of worsening of sexual function after surgery may be related to dyspareunia, reduced lubrication, and/or reduced genital sensation [16]. 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 use suture implantation to study the inflammatory effects of foreign materials [17]. One study reported that postoperative dyspareunia resulted in a deterioration of postoperative sexual function [6]. However, none of the women in our series reported dyspareunia, and the pain scores of all subjects improved at 6 months postoperatively.

In our series we performed two types of TVM procedures for patients with POP. Seven patients with a

cystocele underwent anterior TVM (TVM-A), and 15 patients with apex and posterior vaginal wall prolapse underwent both anterior and posterior TVM (TVM-AP) procedures. In TVM-A, four arms are passed through the obturator foramen to the arcus tendineus fascia pelvis to restore lateral support. In TVM-P, two arms are passed to the sacrospinous ligament to reinforce the sacrouterine ligament by a transgluteal route [2, 6, 8]. Dorsal clitoral neurovascular bundles are paired terminations of the pudendal neurovascular bundles. The clitoral neurovascular bundles ascend along the ischio-pubic rami to meet each other and pass along the superior surface of the clitoral body supplying the clitoris [18]. From an anatomical point of view, therefore, the clitoral neurovascular bundles cannot be damaged during a TVM-P procedure. Between the present TVM-A and TVM-AP groups, there were no significant differences in clitoral blood flow or sexual function changes.

Several multidimensional self-report questionnaires are available to assess sexual function in women, but only the FSFI had been translated and validated in a general Japanese population when we started the present study. The Pelvic Organ Prolapse and Incontinence Sexual Function Questionnaire (PISQ), which is a condition-specific sexual function questionnaire for women with POP or urinary incontinence, has recently been translated and validated in Japanese [19, 20]. Cultural norms often prevent postmenopausal Japanese women from freely discussing their sexual health, which makes assessments based solely on questionnaires unreliable. Therefore, an objective and quantitative method for measuring physiologic components of the sexual response would augment the information gained from questionnaires.

The color Doppler sonographic examination is a

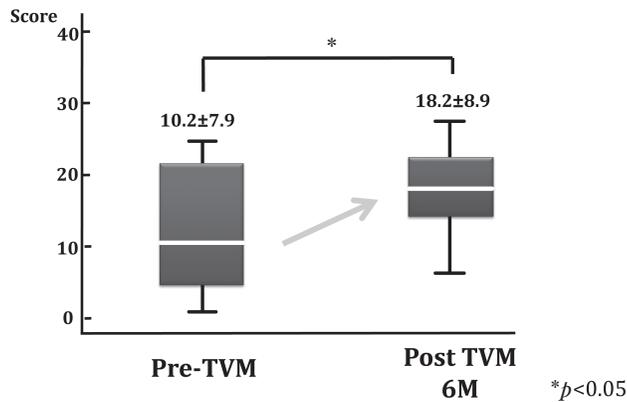


Fig. 5 The total Female Sexual Function Index (FSFI) scores improved significantly from baseline to 6 months postoperatively. TVM, tension-free vaginal mesh.

Table 2 Sexual function score for each sexual function domain

| No. of pt. | Pre-OP 22 | Post-OP 6M 20 | p Value |
|------------------------------|-----------------|------------------|---------|
| Desire | 1.8 ± 0.7 | 2.1 ± 0.9 | 0.05 |
| Arousal | 1.0 ± 1.1 | 2.4 ± 1.8 | <0.001 |
| Lubrication | 1.4 ± 1.8 | 3.1 ± 2.6 | <0.001 |
| Orgasm | 1.3 ± 1.7 | 3.1 ± 2.3 | <0.001 |
| Satisfaction | 2.9 ± 1.5 | 4.0 ± 2.3 | 0.001 |
| Pain | 1.8 ± 2.3 | 3.3 ± 2.7 | 0.04 |
| Overall | 10.2 ± 7.9 | 18.2 ± 8.1 | <0.001 |
| Frequency of sexual activity | 0.9 ± 0.5/month | 1.8 ± 1.4/month | 0.04 |

simple and reproducible technique that provides continuous real-time imaging of the genital circulation with a high anatomic resolution. Color Doppler ultrasonography has become a first-line diagnostic procedure to measure the penile blood flow of men with erectile dysfunction and may also be used to study the female sexual response by measuring clitoral blood flow [4,21]. Alatas *et al.* measured clitoral artery blood flow and evaluated the effects of hormone replacement therapy [4].

Doppler sonography of the clitoral artery, measuring peak systolic velocity, the RI and the PI was performed in 25 postmenopausal women who had been using a continuous regimen of 0.625 mg of conjugated equine estrogens plus 2.5 mg medroxyprogesterone acetate in one tablet daily for approx. 2 years. Thirty-five postmenopausal women who had not used hormone replacement therapy served as a control group. The authors reported that the clitoral artery peak systolic velocities were significantly higher in the postmenopausal women taking hormone replacement therapy compared to the control group (11.8 ± 5.2 cm/s vs. 15.0 ± 5.4 cm/s, $p=0.025$).

In a study by Khalife *et al.*, two independent assessors performed color Doppler ultrasound in a sample of 40 pre- and post-menopausal women. High positive correlations with no significant mean differences between the examiners were found for maximum velocity, resistance, and pulsatility indices [21]. Caruso *et al.* noted a positive correlation between clitoral blood flow and subjective arousal in women with type 1 diabetes who were treated with sildenafil [22]. Thirty premenopausal women affected by type 1 diabetes and treated with insulin therapy and 39 healthy premenopausal women participated in that prospective open-label clinical study. Each diabetic woman received a single oral dose of 100 mg sildenafil with an ultrasound performed at 1 and 4 h after taking sildenafil. The authors reported that the baseline clitoral blood flow of the diabetic women was lower compared to that of the control group at both 1 and 4 h after sildenafil; the mean RI was significantly lower and the mean PI, mean peak systolic velocity, and mean end-diastolic velocity of the clitoral arteries were significantly greater compared to baseline values [22].

To the best of our knowledge, this is the first report measuring clitoral blood flow using color Doppler ultrasonography in women affected by the surgical

repair of POP with TVM. In the early postoperative period, clitoral blood flow may be reduced secondary to the perforation of the paravesical spaces during mesh positioning, with subsequent scarring and reduced elasticity of the vaginal wall. This is consistent with what we observed in the present ultrasound examinations. The reduction of clitoral flow was temporary, and as the clitoral blood flow recovered after 3 months postoperatively, the patients' sexual function also improved.

One limitation of this study is the lack of normative control hemodynamic data, particularly from women without sexual dysfunction. The study is also limited by the short duration of follow-up and the lack of a comparison between patients with or without a recurrence of prolapse and incontinence post-surgery.

In conclusion, color Doppler ultrasonography is a feasible means by which to measure the baseline and post-treatment indices of clitoral blood flow in women after pelvic floor surgery. Clitoral blood flow may be a useful parameter for studies of the genital circulation and sexuality. Additional prospective studies are necessary to further investigate the effect of clitoral blood flow changes on female sexual function and to assess the utility of clitoral ultrasound as a diagnostic and prognostic tool for female sexual dysfunction.

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