

SUBURETHRAL SLINGPLASTY USING A SELF-FASHIONED GYNEMESH FOR TREATING URINARY INCONTINENCE AND ANTERIOR VAGINAL WALL PROLAPSE

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SUMMARY

Objective: This study was conducted to evaluate the effectiveness of self-fashioned Gynemesh for the concomitant treatment of urinary incontinence and anterior vaginal wall prolapse, and the factors involved in mesh erosion.

Materials and Methods: From March 2004 to September 2006, 65 women with urinary incontinence, with or without pelvic organ prolapse or prior surgery for prolapse or incontinence, were recruited for this study. A self-fashioned Gynemesh was used for the concomitant treatment of urinary incontinence and anterior vaginal wall prolapse. Patients in this study underwent suburethral slingplasty and/or concomitant pelvic reconstructive operations. A general linear model univariate analysis was performed to assess the relationships between mesh erosion and various variables.

Results: The mean postoperative follow-up was 33 months. Those patients with anterior wall prolapse presented as completely cured postoperatively. The cure rate for urinary incontinence was 80%, and the improvement rate was 17%. Vaginal mesh erosion was discovered in four patients (6%) during the postoperative follow-up. These four patients remained continent after the removal of the eroded mesh. The interactive effects for mesh erosion by a general linear model analysis were menopausal women with advanced anterior vaginal wall prolapse ($p < 0.05$) and women with advanced anterior vaginal wall prolapse with concomitant sacrospinous ligament fixation ($p < 0.05$).

Conclusion: We found that using self-fashioned Gynemesh for tension-free suburethral and anterior vaginal slingplasty provided a high success rate (97%) in the 3 years of follow-up. Mechanical rejection may be one of the causes of vaginal mesh erosion. [*Taiwan J Obstet Gynecol* 2009;48(1):53-59]

Key Words: suburethral slings, surgical mesh, urinary stress incontinence, vaginal prolapse

Introduction

The suburethral or pubovaginal sling (PVS) is a centuries-old technique for the treatment of urinary incontinence, first described by Von Giordano and Aldridge in the 1900s [1]. Initially, the PVS procedure for treating urinary incontinence acted as a hammock underneath the proximal urethra or bladder neck to adjust and compensate for urogenital muscular defects [2]. The use

of a PVS of synthetic mesh for treating female stress urinary incontinence (SUI), has increased in the past two decades for simplifying the operative procedure, decreasing the operative time, lowering postoperative morbidity, quickening recovery time, and lessening patients' discomfort [3,4]. Most PVSs with autologous or synthetic materials may offer a favorable cure rate. However, these also have various rates of mesh erosion, infection, bladder injury, and difficulty in voiding postoperatively [5,6].

In the 1990s, Petros and Ulmsten [7] proposed the integral theory, the so-called mid-urethra theory from the early 2000s, and postulated that the pubourethral ligament plays an important role in anchoring the anterior vaginal wall which balances the pelvic floor support. They also developed a new surgical procedure known



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as the tension-free vaginal tape (TVT) procedure which places a polypropylene mesh sling in the midurethral position for treating female urinary incontinence. Afterward, many similar new techniques, such as the trans-obturator suburethral suspension, known as outside-in Monarc as first described by Delorme [8] in 2001, and the inside-out, known as inside-out TVT-O as first described by de Leval [9] in 2003, were created for treating urinary incontinence. These various sling procedures have been reported to have excellent short-term or long-term success rates for treating female SUI since the early 2000s [10,11].

In a previous study, we reported on four women who were treated for SUI using synthetic materials that caused vaginal erosion. We proposed using a short strip or patch of synthetic sling instead of full-length synthetic sling grafts for treating SUI to reduce the amount of graft presenting in the wound bed, and to minimize the risk of infection and mesh rejection [12]. The Gynemesh PS (Gynecare, Ethicon Inc., Somerville, NJ, USA) is polypropylene and is designed to be a lightweight, low-density, soft and macroporous mesh with monofilaments and high bursting strength (Prolift Gynecare White Paper; Ethicon Inc.). It may afford excellent strength, durability, less tissue rejection and surgical adaptability with sufficient porosity (pore size, $>75\ \mu\text{m}$) for necessary tissue ingrowth and the avoidance of harboring bacteria [13]. In this observational study, a small group of patients with urinary incontinence and pelvic organ prolapse underwent a combined surgical treatment using the new self-fashioned Gynemesh, which acts as a hammock support underneath the proximal urethra and is a treatment for urinary incontinence with or without anterior vaginal wall prolapse. In this prospective study, we aimed to evaluate the effectiveness of this self-fashioned mesh for the concomitant treatment of SUI and pelvic organ prolapse, and the factors associated with mesh erosion.

Materials and Methods

This prospective study evaluated 65 women who underwent a PVS procedure for the treatment of SUI and/or concomitant pelvic reconstructive surgery for pelvic organ prolapse during the period from March 2004 to September 2006 at Chung Shan Medical University Hospital. The patients enrolled had urinary incontinence with or without pelvic organ prolapse. The preoperative investigation included a detailed history, pelvic examination, urinalysis, and a multichannel urodynamic study. The patients were willing to pay about US\$300 for a Gynemesh (Gynecare, Ethicon Inc.), which is not

covered by the National Health Insurance in Taiwan. All of the women also signed an informed consent form to indicate that they understood that the surgery employed a self-fashioned polypropylene mesh for urinary incontinence and anterior vaginal wall prolapse. The associated pelvic floor reconstruction surgeries in this study included any of the following, alone or in combination, depending on the site(s) of the defect: vaginal hysterectomy, anterior colporrhaphy, posterior colporrhaphy, or sacrospinous ligament fixation (SSLF) which might be performed to correct the associated pelvic organ prolapse. All terminology, definitions, and the pelvic organ prolapse quantification (POP-Q) system were approved by the International Continence Society [14,15], with the exception of special descriptions.

All patients underwent this procedure under general anesthesia. Before the PVS procedure, a self-fashioned mesh was prepared by trimming the Gynemesh (10 cm in width and 15 cm in length) and sewing it with 1-0 Vicryl (Ethicon Inc.) synthetic absorbable sutures along both ends (Figure A). The tension-free PVS procedure performed underneath the urethra was somewhat different from what was described in our previous study [16]. We used 1-0 Vicryl synthetic absorbable sutures along both ends, instead of 1-0 Ethibond (Ethicon Inc.) nonabsorbable sutures used in our previous study. This is because one woman experienced 1-0 Ethibond suture migration into her bladder cavity [12]. The procedure was as follows: the bladder neck was identified by gently pulling the Foley catheter. A midline anterior vaginal incision was made at the level of the proximal urethra to create a tunnel underneath the pubourethral ligament on either side of the urethra. The Retzius space was not entered. The Stamey needle was introduced from the abdominal incision (0.5 cm each side) and passed blindly through the retropubic space, against the posterior aspect of the pubic bone. The tip of the needle was advanced into the tunnel between the pubourethral ligament and the underlying vaginal mucosa, threaded with 1-0 Vicryl suture material, and withdrawn from the suprapubic incision. The 1-0 Vicryl was pulled until the edge of the attached Gynemesh passed through the endopelvic fascia, and it was then anchored into the arcus tendineus fascia pelvis. The procedure was repeated on the other side. The Gynemesh was placed without tension underneath the bladder neck and proximal urethra as well as the supporting part of the anterior vaginal wall (Figure B). The concomitant pelvic reconstruction surgery was performed using the methods as described by Huang et al [17]. In the first 25 patients, the suburethral mucosa and anterior vaginal wall were closed using simple interrupted sutures. We then switched to the Smead-Jones suturing method

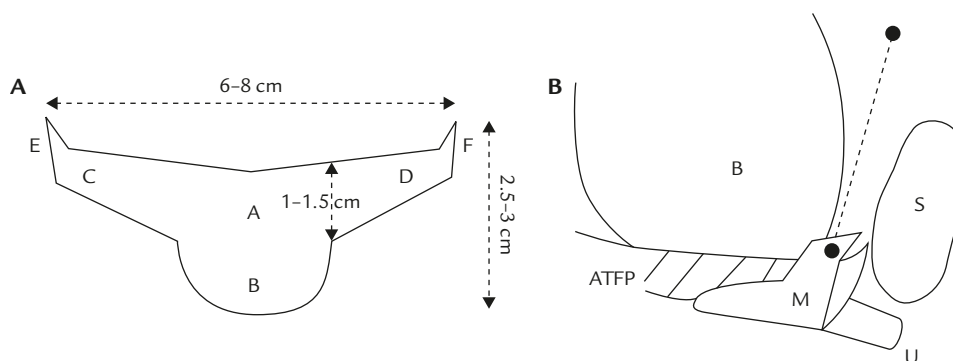


Figure. (A) A self-fashioned Gynemesh with bilateral ends (E and F arms) is sewn using 1-0 Vicryl to reinforce the proximal urethra as a hammock support and the lower portion of the anterior vaginal wall as a graft support. Point A (suburethral part) is placed underneath the mid-urethra and the bladder neck, and B (anterior vaginal part) supports the anterior vaginal wall. The C and D arms lie underneath the paravaginal fascia and are anchored into the arcus tendineus fascia pelvis (ATFP). (B) The Gynemesh is placed underneath the bladder neck and proximal urethra as well as supporting the anterior vaginal wall. The broken line means 1-0 Vicryl is pulled until both ends of the mesh pass through the endopelvic fascia and anchor into the ATFP. B = urinary bladder; S = pubic symphysis; U = urethra; M = Gynemesh.

[18] in the other 40 patients. We expected the Smead-Jones suturing method to increase the vaginal mucosal cushion underneath the urethra and to decrease mesh erosion in this study.

The indwelling Foley catheter was removed 48 hours after surgery, and postvoid residual urine volumes were measured by catheterization after spontaneous voiding by the patients. Postoperative voiding difficulty was defined as a postvoid residual volume of more than 100 mL. All of the patients returned to the outpatient clinic within 1 week of being discharged, and urinalysis and/or urine culture was carried out to check for urinary tract infections. The patients were considered cured if they had a negative stress test and no urine leakage during stress. Patients were considered to have improved if no leakage occurred on the stress test and only occasional leaks were observed during abdominal stress. Failure was defined as unchanged or persistent urine leakage symptoms. A postoperative cure of anterior vaginal wall prolapse was defined as no prolapse or stage I according to the POP-Q system. A follow-up urodynamic study was not routinely performed, unless indicated by urinary symptoms. The postoperative follow-up lasted at least 1 year to assess the postoperative urinary continence and anterior wall prolapse and to record the outcomes and possible complications.

Whether the patients were in menopause, had advanced anterior vaginal wall prolapse (POP-Q, anterior vaginal wall prolapse stage III and IV) or underwent SSLF or Smead-Jones suturing method were considered as possible factors influencing mesh erosion. We used a general linear model univariate analysis to assess the relationships between mesh erosion and various variables simultaneously. All analyses were performed using

SPSS version 10.0 software (SPSS Inc., Chicago, IL, USA), and statistical significance was defined as a *p* value < 0.05.

Results

The mean age of the patients was 56.8 years (range, 35–78 years) and 39 patients were menopausal with a mean age of 61.2 years (range, 48–78 years). The median parity was 3 (range, 1–8). The basic characteristics of our patients, preoperative urodynamic diagnoses, and their concomitant pelvic floor reconstruction procedures are shown in Table 1. Their mean postoperative follow-up was 33 months (range, 18–45 months).

Patients with anterior vaginal wall prolapse presented as completely cured postoperatively. The postoperative cure rate for urinary incontinence was 80% (52/65) and the improved rate was 17% (11/65). Only one patient, with urodynamic stress incontinence and with a history of a radical hysterectomy and pelvic lymph node dissection in 1994 because of cervical cancer of the uterus (stage Ia), failed this PVS procedure. Three patients had postoperative voiding difficulty (postvoid residual urine > 100 mL), including two patients with preoperative voiding difficulty. One of these two patients had preoperative residual urine of 300 mL and the other 150 mL because of preoperative vault prolapse with urethral kicking and voiding difficulty with a positive stress test after reduction. These three patients had a Foley catheter inserted before they were discharged from the hospital. Two of these three patients were able to urinate (residual urine, < 100 mL) within 1 week of being discharged. The Foley catheter was then removed.

Table 1. Patients characteristics and their clinical diagnoses (*n* = 65)

Age (yr)	56.8 (35–78)
Parity, median (range)	3 (1–8)
Age of menopausal women (<i>n</i> = 39), mean (range) (yr)	61.2 (48–78)
Urodynamics, <i>n</i> (%)	
Urodynamic stress incontinence	27 (41.5)
Mixed incontinence	38 (58.5)
Pelvic organ prolapse (<i>n</i>)	
Uterine/vault prolapse	42
Stage I	17
Stage II	10
Stage III/IV	15
Anterior vaginal wall prolapse	47
Stage I	7
Stage II	21
Stage III/IV	19
Posterior vaginal wall prolapse	45
Stage I	10
Stage II	22
Stage III/IV	13
Operations, <i>n</i> (%)	
PVS only	3 (4.6)
Concomitant PVS and pelvic reconstructive surgery	62 (95.4)
Postoperative follow-up, mean (range) (mo)	33 (18–45)

PVS = pubovaginal sling.

Only one of these patients with preoperative voiding difficulty still had postoperative voiding difficulty and was instructed to perform self-catheterization twice a day postoperatively (after voiding before sleep and after first voiding upon waking). Three patients were diagnosed with urinary tract infections by urine cultures within 1 week of being discharged. These patients were treated and cured with oral antibiotics. One of the 27 patients with urodynamic stress incontinence presented with *de novo* urgency and one of the 38 patients with mixed-type incontinence complained of urgency symptoms after this surgery.

Patients in Cases 1, 2, 3 and 4 were diagnosed postoperatively with vaginal mesh erosion after months 1, 5, 6 and 22, respectively (Table 2). The suburethral mucosa and anterior vaginal wall of the first two patients were closed using simple interrupted sutures after the redundant vaginal wall was trimmed. Closure in the other two patients was performed using the Smead-Jones

suturing method to increase the mass cushion on the suburethral mucosa, but vaginal erosion occurred on the cuff as a result of folding of the mesh. Under intravenous general anesthesia, the exposed vaginal mesh, which was impairing the vaginal mucosa, was removed. These meshes were sent for pathologic analysis, and marked inflammation and fibrotic changes around the fragmented meshes were found. None of these four patients had recurrent urinary incontinence after the removal of the exposed vaginal mesh.

In order to elucidate the important determinants of mesh erosion, a general linear model univariate analysis was performed (Table 3). The model accounted for 12% of the variance (adjusted $r^2 = 0.121$). Menopause, advanced anterior vaginal prolapse, SSLF and the Smead-Jones suturing method did not present significant contributions to mesh erosion. The interactive effects for mesh erosion were menopausal women with advanced anterior vaginal prolapse ($p = 0.017$) and women with advanced anterior vaginal prolapse who had the SSLF procedure ($p = 0.031$).

Discussion

Our study revealed a high success rate (97%) for this combined surgery using a self-fashioned Gynemesh for treating urinary incontinence (cure rate, 80%; improvement rate, 17%) and anterior vaginal wall prolapse (complete cure). This result is consistent with our previous study, using self-fashioned polypropylene mesh for PVS in treating urinary incontinence (cure rate, 71.9%; improved rate, 21.1%) [19], and with that of Kuo [20] (overall success rate, 96%). The tissue surrounding the mesh, removed because of vaginal erosion, showed marked inflammation and prominent fibrotic changes in the histologic findings. We hypothesize that the possible mechanism of our method to achieve continence is to induce fibrosis by the sling material to provide competent urethral support. These findings are similar to the results of Chin and Stanton [21]. In the present study, the patients with mesh erosions still remained continent after the suburethral meshes were removed. We believe that the fibrosis formation around the suburethral tissue and paravaginal fascia due to marked inflammation induced by the mesh has worked as a continence mechanism, even after the mesh has been removed. This phenomenon corresponds with other findings [22]. Bent et al [22], for example, found that 75% of patients still remained continent after sling grafts (Gore-Tex; WL Gore & Associates Inc., Flagstaff, AZ, USA) were removed because of vaginal erosion.

Table 2. Characteristics of the four patients with vaginal mesh erosion after concomitant pubovaginal sling (PVS) and pelvic reconstruction surgery

Case	Age (yr)	Diagnosis	Operations	Time, sites and possible cause of vaginal erosion
1	67	Urodynamic stress incontinence, anterior wall prolapse stage II, and posterior wall prolapse stage II	PVS, anterior and posterior colporrhaphy	Postoperative month 1 Mid-line of the suburethral mucosa Impaired vascularity due to over-trimmed suburethral mucosa and poor vaginal mucosa status due to estrogen deficiency
2	54	Mixed incontinence, uterovaginal prolapse stage IV	PVS, anterior and posterior colporrhaphy, vaginal hysterectomy, and sacrospinous ligament fixation	Postoperative month 5 Right lateral recess of the vagina Impaired vascularity due to weakening and over-dissecting of the lateral recess of the vagina and poor vaginal mucosal status estrogen deficiency
3	44	Urodynamic stress incontinence, uterovaginal prolapse stage II	PVS, anterior and posterior colporrhaphy, vaginal hysterectomy, and sacrospinous ligament fixation	Postoperative month 6 Apex of the vaginal cuff Mechanical rejection due to folded mesh
4	59	Mixed incontinence, uterovaginal prolapse stage IV	PVS, anterior and posterior colporrhaphy, vaginal hysterectomy, and sacrospinous ligament fixation	Postoperative month 22 Apex of the vaginal cuff Chronic inflammation and poor vaginal mucosal status estrogen deficiency

Table 3. General linear model univariate analysis with the mesh erosion as the dependent variable

Source	Type III sum of squares	F	p
Corrected model*	1.410*	1.448	0.205
Intercept	0.318	3.915	0.058
Menopause	0.318	3.919	0.058
Advanced cystocele	0.081	0.995	0.327
SSLF	0.273	3.369	0.077
S-J method	0.129	1.593	0.218
Menopause × advanced cystocele	0.529	0.529	0.017 [†]
Menopause × SSLF	0.067	0.824	0.372
Menopause × S-J method	0.067	0.824	0.372
Advanced cystocele × SSLF	0.419	5.163	0.031 [†]
Advanced cystocele × S-J method	0.093	1.149	0.294
SSLF × S-J method	0.067	0.824	0.372

* $r^2 = 0.392$ (adjusted $r^2 = 0.121$); [†] $p < 0.05$. SSLF = sacrospinous ligament fixation; S-J method = Smead-Jones suturing method.

Gynemesh has been designed to decrease infection and tissue rejection and to conform to anatomy, and can lie flat, reinforcing and stabilizing the pelvic fascial structure (Prolift Gynecare White Paper). In an animal

model, the inflammatory and fibrotic reaction of Gynemesh is less than other polypropylene meshes because of its macroporosity, monofilament construction, and soft and flexible response to dynamic force [23].

To the best of our knowledge, the mesh erosion of this material in the treatment of SUI or pelvic organ prolapse has been reported at various rates from 1.3–20% [16,24–27]. Several factors are thought to contribute to mesh erosion, including infections, foreign body reactions, poor healing, poor surgical technique, estrogen deficiency, sexual intercourse too soon postoperatively, excessive sling tension, and vascularity impairment of the vaginal tissue overlying the sling [6,26,27]. Achari et al [28] reported that there was no association between mesh type and mesh erosion, but mesh erosion was associated with a surgeon's experience and the patient's age. Deffieux et al [24] reported a 20% rate of mesh erosion using Gynemesh for transvaginal repair of anterior vaginal wall prolapse and found that patient age of over 70 years was an independent predictive factor for vaginal erosion.

The above findings were somewhat different from ours. The rate of mesh erosion in this study was found to be 6% (4/65). However, menopause, advanced cystocele, whether undergoing SSLF or the Smead-Jones method had no significant effects on mesh erosion. The mean age of menopausal women was 61.2 years in our study. This may be too young; an age of more than 70 years was a predictive factor of vaginal erosion in the study of Deffieux et al [24]. We postulated that the Smead-Jones suturing method would increase the vaginal mucosal cushion underneath the urethra and decrease mesh erosion in this study, but this was not associated with any significant difference. One of the design characteristics of Gynemesh is a soft and flexible response to dynamic force. This may keep the suburethral mesh *in situ* and avoid displacement even if the mesh is folded. This is a good feature but insufficient to prevent possible displacement. Because patients are active, it is impossible to keep patients completely immobile postoperatively. A patient's daily activity may change the dynamic force on the mesh, and this change may displace the mesh's position. A slight displacement may gradually cause the mesh to not lie flat, not conform to the anatomy, and alter the tissue-foreign body reaction. Mesh erosion will occur in this chain reaction, and this is what we call "mechanical rejection" or "mechanical failure".

We hypothesized that the Smead-Jones suturing method would increase the vaginal mucosal cushion to avoid this mechanical rejection and decrease the erosion rate. Our result, however, might have been limited because of the low number of women recruited for this study. Longitudinal studies with larger numbers need to be conducted to clarify this issue. We discovered that two interactive factors had a significant contribution to mesh erosion: menopausal women with advanced anterior

vaginal wall prolapse, and women with advanced anterior vaginal wall prolapse repaired by the SSLF procedure. Mesh erosion does not result from one single factor, but with a combination of factors. According to our findings, we would suggest that menopausal women with advanced anterior vaginal wall prolapse undergo hormone therapy before and after this procedure and consider the SSLF procedure if there is advanced anterior vaginal wall prolapse.

We examined our four patients with vaginal mesh erosion for probable causes and found that the first may have resulted from an overtrimmed suburethral mucosa, the second from a weakened lateral vaginal recess resulting in the impairment of vascularity in the vaginal mucosa, the third from a technical failure of folding the mesh during the closing of the vaginal cuff, and the fourth from mechanical rejection (Table 2). Wang et al [26] reported that the immunohistochemical findings on the removal of eroded mesh demonstrated a host versus graft reaction and defective vaginal healing, but they still remained in doubt about the real causes of mesh erosion. In some studies, microbial biofilms and matrix-enclosed bacterial populations formed within the pore spaces of pore media may have triggered chronic inflammation, accumulating macrophages and monocytes around the monofilament leading to secondary immune rejection and mesh erosion [29,30]. Therefore, the prevention of mesh erosion seems difficult, as it depends not only on well-made materials, but also on the avoidance of infection, good tissue healing, good surgical technique, and other factors that need to be studied. From our experience, we suggest that the redundant vaginal wall should not be overtrimmed, because vaginal mucosa is a very elastic tissue which will shrink back to the fascia layer. The Smead-Jones suture method should be used to close the suburethral mucosa and vaginal wall, tension on the vaginal wall should be lessened during wound closure, and postoperative treatment with estrogen cream for menopausal women may prevent vaginal mesh erosion in these patients.

Using a self-fashioned Gynemesh for suburethral and anterior vaginal slingplasty with a tension-free procedure can provide a high success rate for treating urinary incontinence associated with anterior vaginal wall prolapse. The interactive effects for mesh erosion were menopausal women with advanced anterior vaginal wall prolapse ($p < 0.05$) and women with advanced anterior vaginal wall prolapse with concomitant SSLF ($p < 0.05$). Mechanical rejection may be one of the causes of vaginal mesh erosion. However, it is difficult to overcome this erosion, because its causes require further investigation.

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