Gynecology and Minimally Invasive Therapy 4 (2015) 37–40

Contents lists available at ScienceDirect

Gynecology and Minimally Invasive Therapy

journal homepage: www.e-gmit.com

Original article

Objective and subjective outcome 3 years after synthetic transobturator nonabsorbable anterior mesh use in symptomatic advanced pelvic organ prolapse surgery

Tsia-Shu Lo*, Enie Akhtar bt Nawawi, Pei-Ying Wu, Leng Boi Pue

Department of Obstetrics and Gynecology, Chang Gung Memorial Hospital, Keelung Medical Center, Keelung, Taiwan, ROC

ARTICLE INFO

Article history:
Received 9 October 2014
Received in revised form
15 January 2015
Accepted 23 January 2015
Available online 20 April 2015

Keywords:
pelvic organ prolapse
perigee
sacrospinous fixation
transobturator mesh

ABSTRACT

Background: The management of using a mesh graft in the anterior compartment is reported to lead to a higher rate of recurrent prolapse after anterior colporrhaphy than after mesh repair. Several randomized controlled trials (RCTs) have shown no significantly superior subjective cure rates or reoperation rates, despite better anatomical cure rates with synthetic mesh compared with traditional anterior colporrhaphy for anterior compartment defects, however, the follow-up period in most RTCs was only 1 year.

Objective: To evaluate the objective and subjective outcome in women with symptomatic advanced pelvic organ prolapse (POP) who underwent sacrospinous fixation (SSF) with anterior vaginal mesh (AVM). We postulated that in the hands of well-trained surgeons, AVM plus SSF yields better long-term success rates with a low rate of mesh-related complications. We studied the long-term postoperative outcomes of SSF with AVM.

Study design: This was a retrospective study of 114 patients who underwent surgery for POP between January 2006 and March 2010. Patient assessment at baseline and 3-year postoperative follow-up was analyzed. SSF plus AVM was performed for apical and anterior compartment repair. Primary outcome was objective cure (POP Quantification Stage ≤ 1) and subjective cure defined as a negative response to Questions 2 and 3 on the POP Distress Inventory 6. Secondary outcomes were complications, symptoms severity, and quality of life as measured using validated questionnaires.

Results: Postoperative data for 114 patients were analyzed. Median follow up was 59.6 months. All patients completed a minimum of 3 years follow up. The objective cure rate was 100% for anterior and apical compartments and 90.4% for posterior compartment. Regarding the individual compartment, the cure rate was significantly high ($p < 0.001$ for all compartments).

There were four cases (3.5%) of mesh exposure in which all patients were treated under local anesthetic with excision of the exposed mesh without additional suturing of vaginal tissue at the outpatient office. Topical estrogen therapy was prescribed to facilitate re-epithelialization of vaginal wounds. There were no cases of mesh erosion into the bladder or other organs, and no patient needed mesh removal due to chronic pain or infection.

There was no recurrence in the anterior and apical compartment. Eleven patients (9.6%) had recurrence of the posterior compartment during postoperative follow up.

There was a significant improvements in all questionnaires with $p < 0.001$ for POP Distress Inventory 6, Urogenital Distress Inventory, and Incontinence Impact Questionnaire, and $p = 0.001$ for Prolapse/Urinary Incontinence Sexual Function Questionnaire. There was no significant difference for preoperative and 1-year postoperative urodynamic diagnosis. There were seven cases of occult urodynamic stress incontinence.

Conclusion: The Perigee System gave a favorable result in both anatomical and subjective success rates with a low rate of mesh-related morbidities. The strength of the study reported here is its long-term follow up of a relatively large number of patients and the use of validated questionnaires. Limitations are that it is not a RCT; hence, selection and indication bias is unavoidable. The favorable outcome and

Conflicts of interest: All contributing authors declare no conflicts of interest.

* Department of Obstetrics and Gynecology, Chang Gung Memorial Hospital, Keelung Medical Center, 222, Maijin Road, Keelung, 204, Taiwan, ROC.
E-mail address: 2378@cgmh.org.tw (T.-S. Lo).

http://dx.doi.org/10.1016/j.gmit.2015.01.004

low morbidities resulting from mesh use is from a single surgeon's perspective and may not be generalized to others.

Introduction

Pelvic organ prolapse (POP) may occur in up to 50% of parous women.[1] The lifetime risk of undergoing surgery for POP in the general female population aged ≤ 85 years has recently been reported to be as high as 19–20%.[2,3] This high likelihood of undergoing surgery for POP combined with the knowledge of anatomic failure rates for native tissue repairs, that range between 30% and 70% for the anterior vaginal wall and approximately 20% for the posterior vaginal wall, has led to the increased use of prosthetic mesh in vaginal prolapse surgery with the main aim to reduce anatomic failure rates and increase the durability of repairs.[4–7] The management of using a mesh graft in the anterior compartment is supported by a recent Cochrane review[1] which reported a higher rate of recurrent prolapse after anterior colporrhaphy than after mesh repair. Several randomized controlled trials (RCTs) showed no significantly superior subjective cure rates or reoperation rates despite better anatomical cure rates with synthetic mesh compared with traditional anterior colporrhaphy for anterior compartment defects,[8] however, the follow-up period in most of these RCTs was only 1 year. Therefore the conclusion made by the Food and Drug Administration based on these findings stated that there is no conclusive evidence that using transvaginally placed mesh in POP repair is an improvement over traditional POP repair without mesh and that it may expose patients to greater risks.[9]

Materials and methods

Medical records of 198 patients who underwent primary POP surgery without concomitant anti-incontinence surgery performed between January 2006 and March 2010 were retrospectively reviewed. In total 114 patients who had transvaginal anterior mesh (AVM) plus sacrospinous fixation (SSF) were evaluated. Inclusion criteria comprised patients with POP stages 3 and 4 who underwent primary POP repair. Patients who needed concomitant anti-incontinence surgery, who had previous POP repair, or who were unfit for surgeries were excluded. All patients had preoperative evaluations, including detailed medical history, physical examination, and pelvic examination. Vaginal examinations were done with patients in the semisupine lithotomy position. A split-speculum technique was used to evaluate descent of the vaginal vault, anterior and posterior vaginal walls, and uterine prolapse with maximum Valsalva maneuver. Prolapse staging was recorded according to the POP Quantification (POP-Q) system.[10]

Investigations included urinalysis, 1-hour pad test, cough stress test, and multichannel urodynamic evaluation. All patients were required to complete a 72-hour voiding diary, the Incontinence Impact Questionnaire (IIQ-7),[11] the Urogenital Distress Inventory (UDI-6),[12] the POP Distress Inventory 6 (POPDI-6),[13] and the Prolapse/Urinary Incontinence Sexual Function Questionnaire (PISQ-12)[14] at baseline and during follow up at 12 months and 36 months. Validated Chinese versions were used for all questionnaires.[15] All conditions were defined according to the standards of the International Continence Society.[10]

Patients with poorly controlled medical conditions were optimized before surgery. All patients were counseled on the surgical procedures and informed of the potential benefits and possible complications during and following surgery. Risk of mesh-related complications, e.g., mesh erosion, chronic pelvic pain, dyspareunia, infection, and the possibility of needing additional procedures for mesh removal or trimming in case of mesh complications, were included in the counseling. Patients made an informed decision as to whether to have AVM surgery or not. Postmenopausal patients received preoperative and postoperative topical estrogen treatment unless contraindicated.

Operative procedure

All surgeries were performed by the senior author (T.S.L.), who is experienced in native tissue pelvic reconstructive surgery and trained in vaginal mesh insertion. Surgeries performed include vaginal hysterectomy, anterior vaginal mesh procedure (Perigee System; AMS, Minnetonka, MN, USA) and, if indicated, a posterior colporrhaphy. Right unilateral SSF via a posterior approach, as described by Miyazaki,[16] was adopted for all patients. Details of the surgical procedure for AVM (Perigee) were described previously.[17,18]

Cystoscopy to evaluate the integrity of the lower urinary tract was performed. All patients were given a prophylactic antibiotic of 500 mg cefazolin prior to surgery that continued every 6 hours postsurgery for 1 day. A Foley catheter and a vaginal pack (gauze soaked with povidone iodine) were placed for 72 hours. Catheterization was stopped once the amount of postvoid residual was consistently <20% of that from self-voiding. Patients with a residual urine volume persistently >150 mL for >5 days were taught to use clean intermittent self-catheterization.

Follow-up visits were scheduled at 1 week, 1 month, 3 months, 6 months, 1 year, and annually thereafter. The outcome measure was the objective cure rate at 3 years' follow up, defined as POP-Q ≤ 1 at the anterior vaginal wall and all compartments. Patient feedback on POPDI-6 with no or mild sensation of protruding abdominal organ (Question 3) and no or mild heaviness (Question 2) were considered subjective success.[19]

Descriptive statistics were used for demographics and perioperative data. Paired-sample t test, and either Chi-square or Fisher exact test were applied for comparison of pre- and postoperative continuous and categorical data, respectively. A repeated measures analysis of variance (ANOVA) was used to determine whether a difference in continuous follow up existed between groups in order to decrease the chance of type 1 error. A value of $p < 0.05$ was considered statistically significant for all comparisons. All statistical methods used the commercial software SPSS, version 17 (SPSS, Chicago, IL, USA). The institutional review board of Chang-Gung Memorial Hospital approved the chart evaluation of this study.

Results

Median follow up was 59.6 months. All patients completed a minimum of 3 years follow up. Preoperative demographics are as shown in Table 1. The objective cure rate was 100% for the anterior and apical compartment and 90.4% for the posterior compartment

Table 1
Baseline patient characteristics.

Baseline characteristics	$n = 114$
Age (y)	64.1 ± 11.7
Body mass index (kg/m^2)	25.6 ± 3.6
Parity, median (SD)	4.2 (1.8)
Postmenopausal	93 (81.6)
Concurrent surgery: VH	95 (83.3)

Data are presented as n (%) or mean ± SD unless otherwise stated.
SD = standard deviation; VH = vaginal total hysterectomy.

(Table 2). As for the individual compartment, the cure rate was significantly high ($p < 0.001$ for all compartments; Table 3).

There were four cases (3.5%) of mesh exposure in which all were treated under local anesthetic with excision of the exposed mesh without additional suturing of vaginal tissue at the outpatient office. Topical estrogen therapy was prescribed to facilitate re-epithelialization of vaginal wounds. There were no cases of mesh erosion into the bladder or other organs, and no patient needed mesh removal due to chronic pain or infection.

There was no recurrence in the anterior and apical compartment; 11/114 (9.6%) patients had recurrence of the posterior compartment during postoperative follow up. There was a significant improvement in all questionnaires with $p < 0.001$ for POPDI-6, UDI-6, and IIQ-7 and $p = 0.001$ for PISQ-12 (Table 4); however, there were only 67 patients (58.7%) available for PISQ-12 analysis. There was no significant difference for preoperative and 1-year postoperative urodynamic diagnosis. There were seven cases of occult urodynamic stress incontinence.

Discussion

Demographics in this study showed the mean age was 64.1 years and median parity was 4.2. Another large population study showed that those who underwent vaginal mesh surgery (median 59 years, interquartile range 52–67) were older than those who underwent native tissue repair; (median 55 years, interquartile range 47–63; $p < 0.001$).[20] Age and sexual activity were the significant independent predictors of late mesh exposure in previous studies.[21,22] The objective success rate was high: 90.4% for the posterior compartment and 100% for both the anterior and apical compartment. This is comparable with other studies; which reported an overall success rate of 93.5% at 3 years in a retrospective study utilizing Prolift T, Perigee, and Apogee[23] and 97.1% across all 68 women who were followed up for at least 2 years.[24] None of the recurrence of posterior compartment in our study was reoperated because most had no bothersome symptoms and were asymptomatic. Despite that, they did not report a worsening of prolapse-related symptoms (POPDI-6). The higher success rate of anterior repair in our study is possibly because we combined anterior repair with SSF. Ideal repair of the anterior compartment should include a concomitant apical support procedure because the magnitude of anterior vaginal wall prolapse is a combined function of impairment of the pubovisceral muscle and the uterosacral and cardinal ligaments (apical support).[25,26] The vaginal apex is often involved in large cystoceles; therefore, concomitant apical support is necessary with anterior compartment repair.[27] The significant individual compartment cure rate in all compartments may be explained by ensuring better support for anterior prolapse with the use of synthetic mesh, with less burden being exerted on the apical compartment, together with the performance of SSF leading to a better cure rate and lower recurrence of vault prolapse.

Many previous studies suggested no difference between transvaginal mesh and native tissue repair in term of subjective cure rate and quality of life despite superior objective cure rates in mesh-augmented repair.[28–30] Our study showed a significant improvement of quality of life as shown by the improvement in POPDI-6, PISQ-12, UDI-6, and IIQ-7. The improved postoperative UDI-6 and IIQ-7 scores may imply that the Perigee procedure improves lower urinary tract symptoms. The most frequently observed complication was *de novo* stress urinary incontinence defined as the subjective complaint of stress incontinence after surgery in previously continent women, and this subject matter is currently being analyzed in our ongoing study. Mesh-related vaginal erosion is one of the major drawbacks of this type of surgery, with an average incidence of 10%.[31,32] Notably our mesh exposure rate was 3.5%, which is comparable with the rate reported by Cao et al[33] (3.6%), but much lower than the average reported rate of approximately 10%.[1,31] The low rate shown in our study is probably because we excluded the first 20 cases during the learning curve and patients with previous prolapse surgery. Long et al[23] suggested that vaginal erosion is less likely to occur beyond the learning curve. In addition, using the hydrodissection technique to ensure inclusion of the full thickness of the vagina epithelium and endopelvic fascia, together with not trimming redundant vaginal tissue was adopted in order to minimize the risk of mesh exposure. Some authors suggested

Table 2
Individual compartment cure rate preoperatively and at the 3-year postoperative follow up.

Compartment	Preop POP-Q > 1	Postop POP-Q > 1	p
Anterior	114 (100)	0	<0.001
Apical	114 (100)	0	<0.001
Posterior	114 (100)	11 (9.6)	<0.001

Data are presented as n (%).
POP-Q = Pelvic Organ Prolapse Quantification system staging; Postop = postoperatively; Preop = preoperatively.

Table 3
Pelvic Organ Prolapse Quantification (POP-Q) staging preoperatively and at the 3-year postoperative follow up.

Compartment	Staging	Preop	Postop
Anterior	1	0	114 (100)
$n = 114$	2	5 (4.4)	0
	3	61 (53.5)	0
	4	48 (42.1)	0
Apical	1	0	114 (100)
$n = 114$	2	2 (1.8)	0
	3	71 (62.3)	0
	4	41 (36.0)	0
Posterior	1	0	103 (90.4)
$n = 114$	2	8 (7.0)	8 (7.0)
	3	60 (25.6)	3 (2.6)
	4	46 (40.4)	0

Data are presented as n (%).
Postop = postoperatively; Preop = preoperatively.

Table 4
Quality of life (QOL) scores preoperatively and at the 3-year postoperative follow up.

QOL measurement	Patients with both baseline and 3-year follow-up score			
	Baseline	3-year follow up	Δ Mean ± SD	p
POPDI-6	15.1 ± 3.3	9.8 ± 2.0	−5.2 ± 4.8	<0.001
PISQ-12	23.1 ± 5.0	29.0 ± 5.4	5.9 ± 8.4	0.001
UDI-6	14.1 ± 4.0	9.5 ± 2.9	−4.6 ± 4.5	<0.001
IIQ-7	12.4 ± 5.4	8.3 ± 4.5	−4.1 ± 3.5	<0.001

Data are presented as the mean ± standard deviation.
IIQ-7 = Incontinence Impact Questionnaire (score 0–21); PISQ-12 = Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (score 0–48); POPDI-6 = Pelvic Organ Prolapse Distress Inventory 6 (score 0–24); UDI-6 = Urinary Distress Inventory (score 0–18).

higher mesh exposure with concomitant hysterectomy,[23] however, our findings did not support this association, as we only had 3.5% mesh exposure despite 91.3% (95/114 patients, 83.3%) concomitant vaginal hysterectomy. The other rare complication reported by Long and Wu[33] is the vaginal adhesion band following a transvaginal mesh repair, which needs to be addressed as part of counseling preoperatively.

Conclusion

Transobturator nonabsorbable AVM combined with SSF yielded a favorable and sustainable result over 3 years in anatomical and subjective success rates. The rate of mesh-related morbidities was low and acceptable.

References

1. Maher CM, Feiner B, Baessler K, Glazener CM. Surgical management of pelvic organ prolapse in women: the updated summary version Cochrane review. *Int Urogynecol J*. 2011;22:1445–1457.
2. Smith FJ, Holman CD, Moorin RE, Tsokos N. Lifetime risk of undergoing surgery for pelvic organ prolapse. *Obstet Gynecol*. 2010;116:1096–1100.
3. de Boer TA, Slieker-Ten Hove MC, Burger CW, Kluivers KB, Vierhout ME. The prevalence and risk factors associated with previous surgery for pelvic organ prolapse and/or urinary incontinence in a cross-sectional study in the Netherlands. *Eur J Obstet Gynecol Reprod Biol*. 2011;158:343–349.
4. Altman D, Vayrynen T, Engh ME, Axelsen S, Falconer C. Nordic Transvaginal Mesh Group. Anterior colporrhaphy versus transvaginal mesh for pelvic organ prolapse. *N Engl J Med*. 2011;364:1826–1836.
5. Weber AM, Walters MD, Piedmonte MR, Ballard LA. Anterior colporrhaphy: a randomized trial of three surgical techniques. *Am J Obstet Gynecol*. 2001;185:1299–1304. discussion 1304–1306.
6. Sivaslioglu AA, Unlubilgin E, Dolen I. A randomized comparison of polypropylene mesh surgery with site-specific surgery in the treatment of cystocele. *Int Urogynecol J Pelvic Floor Dysfunct*. 2008;19:467–471.
7. Nguyen JN, Burchette RJ. Outcome after anterior vaginal prolapse repair: a randomized controlled trial. *Obstet Gynecol*. 2008;111:891–898.
8. Keys T, Campeau L, Badlani G. Synthetic mesh in the surgical repair of pelvic organ prolapse: current status and future directions. *Urol J*. 2012;80:237–243.
9. Food and Drug Administration. *Urogynaecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse*; July 2011. Available at: http://www.fda.gov/downloads/medicaldevices/safety/alertsandnotices/ucm262760.pdf.
10. Haylen BT, de Ridder D, Freeman RM, et al. An International Urogynaecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for female pelvic floor dysfunction. *Int Urogynecol J*. 2010;21:5–26.
11. Uebersax JS, Wyman JF, Shumaker SA, McClish DK, Fantl JA. Short form to assess life quality and symptoms distress for urinary incontinence in women: the Incontinence Impact Questionnaire and the Urogenital Distress Inventory. Continence Program for Women Research Group. *Neurourol Urodyn*. 1994;14:131–139.
12. Shumaker SA, Wyman JF, Uebersax JS, McClish DK, Fantl JA. Health-related quality of life measures for women with urinary incontinence: the Incontinence Impact Questionnaire and the Urogenital Distress Inventory. Continence Program in Women (CPW) Research Group. *Qual Life Res*. 1994;3:291–306.
13. Barber MD, Walters MD, Bump RC. Short forms of two condition-specific quality-of-life questionnaires for women with pelvic floor disorders (PFDI-20 and PFIQ-7). *Am J Obstet Gynecol*. 2005;193:103–113.
14. Rogers RG, Coates KW, Kammerer-Doak D, Khalsa S, Qualls C. A short form of the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaires (PISQ-12). *Int Urogynecol J Pelvic Floor Dysfunct*. 2003;14:164–168.
15. Su TH, Lau HH. Validation of a Chinese version of the short form of the pelvic organ prolapse/urinary incontinence sexual questionnaire. *J Sex Med*. 2010;7:3940–3945.
16. Miyazaki FS. Miya hook ligature carrier for sacrospinous ligament fixation. *Obstet Gynecol*. 1987;70:286–288.
17. Rane A, Kannan K, Barry C, Balakrishnan S, Corstiaans LY. A prospective study of the Perigee system for the management of cystoceles: medium-term follow-up. *Aust N Z J Obstet Gynecol*. 2008;48:427–432.
18. Lo TS, Ashok K. Combined anterior trans-obturator mesh and sacrospinous ligament fixation with severe prolapse—a case series of 30 months follow-up. *Int Urogynecol J*. 2011;22:299–306.
19. Lo TS, Tan YL, Khanuengkitkong S, Dass AK. Surgical outcomes of anterior trans-obturator mesh and vaginal sacrospinous ligament fixation for severe pelvic organ prolapse in overweight and obese Asian women. *Int Urogynecol J*. 2013;24:809–816.
20. Jonsson Funk M, Visco AG, Weidner AC, Pate V, Wu JM. Long-term outcomes of vaginal mesh versus native tissue repair for anterior vaginal wall prolapse. *Int Urogynecol J*. 2013;24:1279–1285.
21. Kaufman Y, Singh SS, Alturki H, Lam A. Age and sexual activity are risk factors for mesh exposure following transvaginal mesh repair. *Int Urogynecol J*. 2001;22:307–313.
22. Letouzey V, Deffieux X, Gervaise A, Mercier G, Fernandez H, de Tayrac R. Transvaginal cystocele repair using a tension-free polypropylene mesh: more than 5 years of follow-up. *Eur J Obstet Gynecol Reprod Biol*. 2010;151:101–105.
23. Long CY, Hsu CS, Wu CH, Liu CM, Wang CL, Tsai EM. Three year outcome of transvaginal mesh repair for the treatment of pelvic organ prolapse. *Eur J Obstet Gynecol Reprod Biol*. 2012;161:105–108.
24. Cho MK, Kim CH, Kang WD, Kim JW, Kim SM, Kim YH. Anatomic and functional outcomes with the prolift procedure in elderly women with advanced pelvic organ prolapse who desire uterine preservation. *J Minim Invasive Gynecol*. 2012;19:307–312.
25. Stanford EJ, Cassidenti A, Moen MD. Traditional native tissue versus mesh-augmented pelvic organ prolapse repairs: providing an accurate interpretation of current literature. *Int Urogynecol J*. 2012;23:19–28.
26. Chen L, Ashton-Miller JA, Hsu Y, DeLancey JO. Interaction among apical support, levator ani impairment and anterior vaginal wall prolapse. *Obstet Gynecol*. 2006;108:324–332.
27. Rooney K, Kenton K, Mueller ER, FitzGerald MP, Brubaker L. Advanced anterior vaginal wall prolapse is highly correlated with apical prolapse. *Am J Obstet Gynecol*. 2006;195:1837–1840.
28. Nieminen K, Hiltunen R, Takala T, et al. Outcomes after anterior vaginal wall repair with mesh: a randomized controlled trial with a 3 year follow-up. *Am J Obstet Gynecol*. 2010;203:e231–e238.
29. Withagen MI, Milani AL, de Leeuw JW, Vierhout M. Development of *de novo* prolapse in untreated vaginal compartments after prolapse repair with and without mesh: a secondary analysis of a randomized controlled trial. *Br J Obstet Gynecol*. 2012;119:354–360.
30. Nieminen K, Hiltunen R, Heiskanen E, et al. Symptom resolution and sexual function after anterior vaginal wall repair with or without polypropylene mesh. *Int Urogynecol J Pelvic Floor Dysfunct*. 2008;19:1611–1616.
31. Abed H, Rahn DD, Lowenstein L, Balk EM, Clemons JL, Rogers RG. Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials: a systematic review. *Int Urogynecol J*. 2011;22:789–798.
32. Cao Q, Chen YS, Ding JX, et al. Long-term treatment outcomes of transvaginal mesh surgery versus anterior-posterior colporrhaphy for pelvic organ prolapse. *Aust N Z J Obstet Gynecol*. 2013;53:79–85.
33. Long CY, Wu MP. Dyspareunia caused by a vaginal adhesion band following a transvaginal mesh repair. *Gynecol Minim Invasive Ther*. 2013;2:96–98.