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Original Article

Comparing the midterm outcome of single incision vaginal mesh and transobturator vaginal mesh in treating severe pelvic organ prolapse



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ABSTRACT

Objective: The aim of this study is to compare perioperative parameters and midterm clinical outcomes using two different mesh kits: transobturator vaginal mesh (TVM) (both Perigee and Apogee), versus single incision vaginal mesh (SIM) (combined Elevate anterior/apical system and Elevate posterior/apical system) in treating severe pelvic organ prolapse (POP).

Materials and Methods: This is a retrospective cohort study. During 2008 and 2013, those women with severe POP [POP quantification system (POP-Q), Stage III and Stage IV], who received either TVM or SIM operation, were enrolled for cohort comparison. There were 111 patients in the TVM group, and 136 in the SIM group. Those with an incomplete POP-Q record, or who did not complete postoperative urodynamic study were excluded. Perioperative characteristics and outcomes, postoperative urinary symptoms, urodynamic parameters, prolapse recurrence (defined as the leading edge > 0 using the POP-Q system), and mesh extrusion rate were compared.

Results: There were no differences in the operation time, blood loss, hospital stay, and the postoperative visual analog scale for pain. Urodynamic studies showed improvement in bladder outlet obstruction in both groups. The postoperative stress urinary incontinence was significantly higher in the SIM group. The recurrence of prolapse was comparable between the two groups at a median follow-up of 2 years. The mesh extrusion rate was significantly lower in the SIM group.

Conclusion: At an average of 2 years of follow-up, the mesh extrusion rate was lower in the SIM group than in the TVM group, but there was no difference in postoperative visual analog scale for pain. The postoperative stress urinary incontinence was higher in the SIM group.

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Introduction

Pelvic organ prolapse (POP) is characterized by the abnormal descent or herniation of the pelvic organs, and its incidence increases with age. With the gradual increase in life expectancy, POP has become a common problem of adult women. Vaginal mesh for POP repair was first introduced due to the high recurrence following traditional transvaginal repair. Previous population-based epidemiological studies demonstrated that 11–18.7% of women underwent at least one surgery for POP in their lifetime, with a repeat operation rate of 12–30% [1,2]. According to the Cochrane database in 2013, permanent mesh has superior

outcomes and lower recurrence rates in treating anterior compartment prolapse compared to traditional native tissue repair [3]. However, there are also drawbacks to these artificial materials. The US Food and Drug Administration issued a formal warning of complications of vaginal mesh procedures in 2008 [4]. The warning was reiterated and emphasized in 2011, with the most frequent complications being mesh exposure, pain, and urinary problems [5].

The Perigee/Apogee (transobturator vaginal mesh, TVM) system (American Medical Systems, Minnetonka, MN, USA) is a trocar-guided transobturator, type 1 polypropylene vaginal mesh for treating POP. The anterior/apical and posterior/apical Elevate repair system (American Medical Systems) applies a single incision vaginal mesh (SIM) using lighter, softer type 1 polypropylene mesh. Previous studies confirmed the efficacy of both the Perigee/Apogee and Elevate vaginal mesh systems for treating POP [6–10]. However, only a few studies directly compare these two types of mesh procedures [11].

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A recently published study [11] compared the Elevate anterior/apical system with the Perigee system plus sacrospinous ligament fixation (SSF). The investigators concluded that both have comparable anatomical outcomes in treating POP, with the Elevate system provoking more postoperative *de novo* stress urinary incontinence (SUI). All of the recurrences in the study occurred in the posterior compartment.

We compared the TVM and SIM systems for treatment of both the anterior and posterior compartment POP for an average of 2 years. We hypothesize that the SIM has less mesh-related complications with similar anatomical support compared with the TVM at a median of 2-year follow up. The perioperative outcomes, anatomical outcomes, recurrence of prolapse, and mesh extrusion rates were analyzed.

Materials and methods

After obtaining ethical approval from the hospital Institutional Review Board, we conducted a retrospective chart review of patients who received the TVM system from May 2008 through December 2010, and those who received the SIM system from November 2010 through October 2013. The average follow-up times were 32 months (14–73 months) in the TVM group and 25 months (15–47 months) in the SIM group. The inclusion criteria were severe POP, defined as Stage III or Stage IV in the POP quantification system (POP-Q) [12], and having undergone TVM or SIM for prolapse repair. We excluded patients who underwent only single-compartment vaginal mesh repair, patients with incomplete POP-Q assessments during follow-up, and patients who did not complete the postoperative urodynamic studies. Two experienced urogynecologists performed all operations.

All patients received thorough preoperative evaluations including detailed medical histories, physical examinations, pelvic examinations, preoperative pelvic ultrasounds, Pap smears, and urodynamic studies. Prolapse staging was recorded using the POP-Q system. Perioperative parameters included operative time, blood loss, length of hospital stay, and postoperative visual analog scale (VAS) pain score on postoperative Day 1. The frequency of postoperative transient, intermittent catheterization procedures (ICP) was recorded.

Follow-up visits were scheduled for postoperative Week 1, the 1st, 3rd, 6th, and 12th months, and then annually after that. Symptoms of SUI and overactive bladder were recorded, and pelvic examinations were performed in our outpatient department at every postoperative visit. The follow-up POP-Q score and exposure of any mesh including size, location, and exposure management were also recorded. Postoperative urodynamic studies were done 6 months after the operation.

The TVM system was applied using the techniques described by Erickson [13], with only subtle modification. Instead of inserting the needle into the iliococcygeus muscle, we penetrated the sacrospinous ligament to achieve Level I support. The SIM system was applied using the techniques previously described by Huang et al [14].

The vaginal wall was closed in two layers using 2-0 Vicryl (Ethicon, Somerville, NJ, USA). Cystoscopy and digital rectal examination were performed after the placement of the mesh. A Foley catheter and vaginal gauze were placed after the operation and removed on postoperative Day 2. Postoperative, transient ICP was performed after the removal of the Foley catheter when the postvoid residual volume was more than 100 mL on the bladder scan.

The Chi-square test was used to compare binomial variables while the Student paired *t* test was used to compare the preoperative and postoperative data. Additionally, the independent *t* test was used to compare continuous unpaired data. A Kaplan–Meier analysis with a log-rank test was used to compare assumed time-

related variables such as recurrence and mesh exposure rates. All the statistical analyses were performed using IBM SPSS Statistics 22 (IBM Corp., Armonk, NY). Differences were considered statistically significant when $p < 0.05$.

Results

During the study period, 274 patients met the inclusion criteria of undergoing both the anterior/apical and posterior/apical Elevate procedure, or both the Perigee and Apogee procedures for POP repair. Of these, 253 patients had Stage III or Stage IV POP, and among them, eight had incomplete POP-Q records or did not complete the postoperative urodynamic studies. Finally, there were 111 patients in the TVM group and 136 patients in the SIM group.

Table 1 shows the patients' demographic data. There were no differences between the groups in terms of body weight, body mass index, parity, diabetes, menopausal status, or previous related surgeries. The mean patient age in the SIM group was slightly older than in the TVM group (65.8 vs. 63.1 years, $p = 0.03$). Of all patients, 45% in the TVM group and 16.9% in the SIM group underwent uterus-sparing operations. Concurrent vaginal hysterectomies were performed in 33.4% of patients in the TVM group and 64.7% in the SIM group. Concurrent midurethral sling operations were performed in 58.6% of the patient in the TVM group and 22.8% in the SIM group.

The preoperative POP-Q measurement showed more severe prolapse in the posterior compartment in patients treated using the Elevate system (Table 2). Nonetheless, no significant differences in the postoperative anatomical outcomes between the TVM and SIM groups occurred. The urodynamic parameters showed improved bladder outlet obstruction in both groups (Table 3). The maximal urethral closure pressure (MUCP) in both groups decreased postoperatively. The preoperative maximal urine flow rate was higher in the SIM group; otherwise, there were no significant differences in either group when comparing the preoperative and postoperative urodynamic parameters (Table 3).

Table 4 shows the perioperative outcomes. To avoid the inherent, time-consuming nature of combined surgeries that could

Table 1
Patient demographic data.

| | TVM ^a (n = 111) | SIM ^b (n = 136) | p |
|---|----------------------------|----------------------------|--------|
| Mean age (y) | 63.1 ± 9.49 | 65.8 ± 9.84 | 0.032 |
| Mean BMI | 24.8 ± 2.99 | 24.9 ± 3.63 | 0.830 |
| Mean parity | 3.6 ± 1.36 | 3.4 ± 1.34 | 0.248 |
| Diabetes (n) | 22 (19.8%) | 33 (24.2%) | 0.421 |
| Menopausal status (n) | 98 (88.2%) | 123 (90.4%) | 0.707 |
| Previous related surgery (n) | 25 (22.5%) | 27 (19.9%) | 0.600 |
| STH | 3 | 2 | |
| ATH | 4 | 17 | |
| LAVH | 9 | 4 | |
| VTH | 7 | 2 | |
| Anterior/posterior repair | 9 | 1 | |
| Without mesh | 8 | 0 | |
| With mesh | 1 | 1 | |
| Any other prolapse surgery ^c | 2 | 1 | |
| Incontinence surgery ^d | 2 | 2 | |
| Preserve uterus (n) | 50 (45.0%) | 23 (16.9%) | <0.001 |
| Combined VTH (n) | 38 (34.2%) | 88 (64.7%) | <0.001 |
| Combined sling (n) | 65 (58.6%) | 31 (22.8%) | <0.001 |

Mean ± standard deviation (95% confidence interval or percentile).

ATH = abdominal total hysterectomy; BMI = body mass index; LAVH = laparoscopic-assisted vaginal hysterectomy; SIM = single incision vaginal mesh; STH = subtotal hysterectomy; TVM = transobturator vaginal mesh; VTH = vaginal hysterectomy.

^a TVM: Perigee + Apogee.

^b SIM: anterior Elevate + posterior Elevate systems.

^c Any other prolapse surgery: Right side sacrospinous ligament suspension, hysterocolpopexy, or unknown.

^d Incontinence surgery: Burch or sling operation.

Table 2

Pelvic organ prolapse quantification system (POP-Q) staging preoperatively and postoperatively of patients undergoing transobturator vaginal mesh (TVM) and single incision vaginal mesh (SIM).

| | TVM ^a (n = 111) | | | SIM ^b (n = 136) | | | Between groups <i>p</i> | |
|-----------------|----------------------------|-------------|----------|----------------------------|-------------|----------|-------------------------|---------|
| | Pre-op | Post-op | <i>p</i> | Pre-op | Post-op | <i>p</i> | Pre-op | Post-op |
| Aa ^c | 2.9 ± 0.30 | −2.9 ± 0.13 | <0.001 | 2.9 ± 0.27 | −2.9 ± 0.22 | <0.001 | 0.632 | 0.145 |
| Ba ^d | 4.6 ± 1.09 | −3.0 ± 0.67 | <0.001 | 4.5 ± 1.37 | −3.0 ± 0.53 | <0.001 | 0.730 | 0.235 |
| C ^e | 4.2 ± 1.67 | −7.5 ± 0.89 | <0.001 | 4.5 ± 1.52 | −7.2 ± 1.66 | <0.001 | 0.072 | 0.100 |
| Ap ^f | 2.5 ± 0.79 | −3.0 ± 0.00 | <0.001 | 2.5 ± 0.84 | −2.9 ± 0.12 | <0.001 | 0.623 | 0.158 |
| Bp ^g | 3.4 ± 1.50 | −3.0 ± 0.47 | <0.001 | 3.9 ± 1.74 | −3.0 ± 0.12 | <0.001 | 0.025 | 0.159 |
| D ^h | 2.1 ± 2.28 | −8.1 ± 0.71 | <0.001 | 3.9 ± 2.00 | −7.8 ± 1.03 | <0.001 | <0.001 | 0.140 |
| TVL | 7.5 ± 1.02 | 7.8 ± 0.93 | <0.001 | 7.3 ± 0.85 | 7.6 ± 0.89 | <0.001 | 0.291 | 0.111 |

Mean ± standard deviation (95% confidence interval or percentile).

Post-op = postoperative; Pre-op = preoperative; SIM = single incision vaginal mesh; TVL = total vaginal length (cm).

^a TVM: Perigee + Apogee.

^b SIM: Elevate anterior + Elevate posterior.

^c Aa: Anterior vaginal wall 3 cm proximal to the hymen.

^d Ba: Most distal position of the remaining upper anterior vaginal wall.

^e C: Most distal edge of cervix or vaginal cuff scar.

^f Ap: Posterior vaginal wall 3 cm proximal to the hymen.

^g Bp: Most distal position of the remaining upper posterior vaginal wall.

^h D: Posterior fornix (N/A if posthysterectomy).

Table 3

Urodynamic data preoperatively and 6 months postoperatively of two systems.

| | TV ^a (n = 111) | | | SIM ^b (n = 136) | | | Between group <i>p</i> | |
|-------|---------------------------|----------------|----------|----------------------------|----------------|----------|------------------------|---------|
| | Pre-op | Post-op | <i>p</i> | Pre-op | Post-op | <i>p</i> | Pre-op | Post-op |
| Maxfr | 16.1 ± 9.65 | 25.2 ± 30.64 | 0.003 | 19.3 ± 11.43 | 25.3 ± 9.69 | <0.001 | 0.019 | 0.963 |
| Afr | 5.9 ± 3.89 | 8.3 ± 4.29 | <0.001 | 6.2 ± 4.10 | 9.2 ± 6.01 | <0.001 | 0.562 | 0.239 |
| VV | 220.2 ± 149.62 | 295.5 ± 148.31 | <0.001 | 253.4 ± 183.34 | 316.7 ± 134.48 | 0.001 | 0.055 | 0.273 |
| RU | 82.2 ± 56.63 | 37.8 ± 64.98 | <0.001 | 98.6 ± 93.27 | 34.8 ± 42.61 | <0.001 | 0.117 | 0.681 |
| MUCP | 73.7 ± 30.39 | 66.3 ± 32.80 | 0.027 | 68.5 ± 34.52 | 57.2 ± 27.55 | 0.003 | 0.202 | 0.068 |
| FL | 31.5 ± 10.60 | 29.8 ± 11.67 | 0.220 | 31.9 ± 35.58 | 28.9 ± 25.20 | 0.488 | 0.959 | 0.791 |

Mean ± standard deviation (95% confidence interval or percentile).

Afr = average flow rate; FL = functional length; Maxfr = maximal flow rate; MUCP = maximal urethral closure pressure; Post-op = postoperative; Pre-op = preoperative; RU = residual urine; SIM = single incision vaginal mesh; TVM = transobturator vaginal mesh; VV = void volume.

^a TVM Perigee + Apogee.

^b SIM Elevate anterior + Elevate posterior.

Table 4

Perioperative outcomes, excluding combined VTH and sling operation.

| | TVM ^a (n = 31) | SIM ^b (n = 35) | <i>p</i> |
|----------------------|---------------------------|---------------------------|----------|
| Operative time (min) | 94.3 ± 25.10 | 94.2 ± 20.99 | 0.982 |
| Blood loss (mL) | 70.1 ± 43.02 | 85.1 ± 39.36 | 0.144 |
| Hospital stay (d) | 5.0 ± 1.68 | 5.6 ± 2.47 | 0.220 |
| VAS pain score | 4.7 ± 1.68 | 4.1 ± 1.20 | 0.089 |

Mean ± standard deviation (95% confidence interval or percentile).

SIM = single incision vaginal mesh; TVM = transobturator vaginal mesh; VAS = visual analog scale; VTH = vaginal hysterectomy.

^a TVM Perigee + Apogee.

^b SIM Elevate anterior + Elevate posterior.

influence the outcome of the analysis, we excluded the patients that underwent concomitant vaginal total hysterectomies or sling operations. There was no significant difference in the operating time, blood loss, length of hospital stay, or postoperative VAS pain score (with buttock soreness and pain being the most frequent complaint). We also excluded the patients with concurrent sling operations for the assessment of postoperative urinary symptoms. The incidence of postoperative SUI was higher in the SIM group (38.1% vs. 21.7%, $p = 0.04$; Table 5). There were no significant differences in postoperative, transient ICP, or postoperative overactive bladder.

The Kaplan–Meier survival curve for prolapse recurrence, defined as leading edge prolapse > 0, was 4.5% in the TVM group and 2.9% in the SIM group ($p = 0.64$). Figure 1 depicts the mesh

Table 5

Postoperative urinary symptoms, excluding combined sling operation.

| | TVM ^a (n = 46) | SIM ^b (n = 105) | <i>p</i> |
|-----------------------------|---------------------------|----------------------------|----------|
| Transient postoperative ICP | n = 13 (28.3%) | n = 34 (25.7%) | 0.744 |
| Postop SUI | n = 10 (21.7%) | n = 40 (38.1%) | 0.036 |
| Postop OAB | n = 48 (30.4%) | n = 48 (35.2%) | 0.566 |

ICP = intermittent catheterization procedure; OAB = overactive bladder; SIM = single incision vaginal mesh; SUI = stress urinary incontinence; TVM = transobturator vaginal mesh.

^a TVM Perigee + Apogee.

^b SIM Elevate anterior + Elevate posterior.

exposure rate related to time. The exposure rate was 11.7% in the TVM group and 1.5% in the SIM group ($p = 0.01$).

Discussion

The urogynecology community is currently concerned about the complications that have occurred after synthetic vaginal mesh repairs for POP. The erosion rate is of particular interest. In our study, a significantly higher mesh extrusion rate was noted in the TVM group when compared to the SIM group.

Many studies have confirmed the efficacy of the SIM and TVM systems for treating POP. Rapp et al [7] concluded that the anterior and apical Elevate prolapse repair system had good anatomical outcomes 2 years after treatment of anterior and apical prolapse. Su

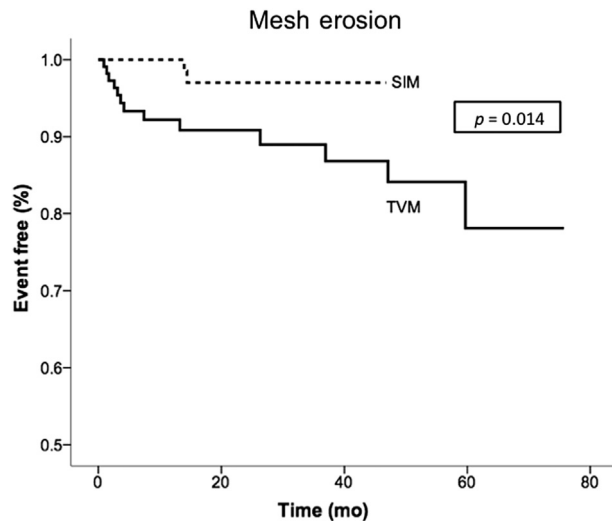


Figure 1. Kaplan–Meier event-free survival of the transobturator vaginal mesh (TVM) and single incision vaginal mesh (SIM) groups during the study period: patient free from mesh extrusion in the two groups ($p = 0.014$).

et al [6] compared the Elevate system with native tissue repair and concluded that it was superior to native tissue repair in the anterior compartment. Furthermore, Chu et al [15] reported an average 98% anatomical cure rate using the Perigee and Apogee systems for POP repair.

Currently, there are few studies that compare the Elevate anterior/apical and posterior/apical systems with the Perigee and Apogee systems for the treatment of POP. Lo et al [11] compared the Elevate anterior/apical system and the Perigee system with SSF. They found that the Elevate system offered anatomical outcomes comparable to the Perigee system with SSF [4]. Nonetheless, they also found higher postoperative *de novo* SUI. All of the recurrences reported by Lo et al [11] arose in the posterior compartment, and they concluded that there is room for further study. In addition, a previous study showed that using vaginal mesh to treat only one compartment of prolapse may provoke the development of prolapse in another compartment that was initially unaffected [16]. Due to these reasons, we included patients who received vaginal mesh treatment for anterior and posterior compartment prolapse in our study. When applying the mesh to the combined anterior and posterior compartments, both study groups had high success rates for anatomical repair, with no increase in the mesh extrusion rate.

The average age in the SIM group was older than in the TVM group, which could be the result of the less invasive nature of the SIM system, facilitating the doctor treating more aggressively in older patients.

In our country, the National Health Insurance Program covers the transobturator tape procedure for anti-incontinence surgery, while the single-incision sling is not included. We used the Monarc (American Medical Systems), a transobturator midurethral sling for anti-incontinence operation, which results in two penetrating skin wounds for anti-incontinence in the TVM group; and Mini-arc (American Medical Systems), a single-incision midurethral sling, in the SIM group. During the preoperative counseling, most patients in the SIM group could not accept having extra two penetrating skin wounds for the anti-incontinence tape, which was covered by the national insurance. As a result, the percentage of concomitant sling operations was much lower in the SIM group. The hysterectomy rate was greater in the SIM group than in the TVM group because older woman tended to request POP repair in

combination with a hysterectomy. Chu et al [15] compared patients receiving the Perigee or Apogee procedures with or without a vaginal hysterectomy and found that the postoperative anatomical outcomes and complication rates were comparable in the two groups. Carramao et al [4] also reported similar outcomes and complication rates between vaginal hysterectomy and uterus-preserving vaginal mesh surgery.

The postoperative urodynamic studies in both the TVM and SIM groups showed improvement in bladder outlet obstruction due to the restoration of the anatomy. There were reductions in postoperative MUCP in both groups. The SIM group had significantly lower MUCP than did the TVM group. Studies have shown reduced MUCP following vaginal mesh surgery [10,11]. The reduction of the postoperative MUCP could result from the disappearance of the urethral pressure caused by preoperative urethral kinking due to the prolapsed organ [17]. The lower MUCP in the SIM group was similar to the results reported by Lo et al [11]. They suggested that it could be due to the extensive dissection required in the SIM group, which caused more tissue damage and denervation.

The postoperative SUI is higher in the SIM group in our study (excluding those with concomitant sling operation), which is in line with the previous study [11]. It had been postulated that higher *de novo* SUI may result from more extensive destruction of the paravesical space in the SIM group compared to the TVM group, causing tissue damage and denervation. The age in the SIM group was slightly older than that in the TVM group. According to several population-based epidemiological surveys, age has now been considered one of the risk factors for all kinds of incontinence [18,19]. Chang et al [20] also reported age as a risk factor for SUI in women aged over 60 years in Taiwan, although in a subgroup of patients (women with hypertension). However, the difference of age between the two groups in our study was 2.7 years, i.e., 63.1 years in the TVM group and 65.8 years in the SIM group; but the postoperative SUI rate was 21.7% in the TVM group and 38.1% in the SIM group. Hannestad et al [18] reported that the prevalence of SUI is 10.92% in the 60–64 years age group, and 10.26% in the 65–69 years age group. In addition, age seems to contribute more in urge incontinence and mixed incontinence [19]. As a result, the higher postoperative SUI in the SIM group may not be related to its older age. Another concern is that the rate of concurrent hysterectomy is higher in the SIM group (64.7%) than in the TVM group (34.2%). To date, there is contradicting evidence on whether hysterectomy has a negative effect on SUI. Some suggested no association between hysterectomy and SUI [20,21]. There was also evidence that suggested hysterectomy as a risk factor for urinary incontinence. Altman et al [22] conducted a 30-year-nationwide, population-based cohort study, and found that those who received hysterectomy have a risk of receiving surgery for SUI twice as high as those who did not. Another study using data from the Women's Health Initiative Observational study with a cohort of > 90,000 women concluded that the risk of hysterectomy was associated with increased urinary incontinence (including SUI) with an odds ratio of 1.2 [23]. Hsieh et al [24] conducted a nationwide epidemiologic study in Taiwan, and reported higher prevalence of urinary incontinence in women who received hysterectomy, and were unrelated to the type of hysterectomy, indication, or time after surgery. However, in our study, patients not only received a hysterectomy but also underwent vaginal mesh augmentation, which involved extensive dissection in the paravesical space. We should apply the results of the above studies to our cases with care.

The anatomical success rate in our study is comparable to that of Lo et al [11] who reported a success rate of 96.9% with the anterior Elevate system and 93.0% for the combined Perigee and SSF procedures 1 year after surgery. Su et al [6] reported a success rate of 97% with the combined anterior and posterior Elevate systems1

year after surgery. Long et al [9] reported a success rate of 96.3% with the combined Perigee and Apogee systems 20 months after surgery. Our study showed that combined anterior and posterior vaginal mesh procedures result in greater anatomical restoration success, without increasing the complication rate compared with applying only the anterior vaginal mesh procedure. Both the SIM and TVM groups had comparable anatomical outcomes at an average follow-up of 2 years.

Recently, additional concerns have emerged regarding the complications of vaginal mesh surgery, mostly involving the erosion of the mesh. Our findings showed that the SIM group had a lower mesh extrusion rate than the TVM group (Figure 1), and the two survival curves diverged at the beginning of the follow-up period. The definition of mesh exposure, according to the International Urogynecological Association/International Continence Society classification of complications [25], is the situation of displaying, revealing, exhibiting, or making accessible the vaginal mesh through the vaginal epithelium. During the 1st month of postoperative healing, scar tissue reaches approximately 40% of its final strength and continues to increase for 1 year after injury [26]. We postulated that there were two different reasons for the different erosion rates of the two mesh procedures. Shortly after the operation, during the initial healing process, poor wound healing causing wound dehiscence could have accounted for the higher rate of erosion in the TVM group. Alternatively, the higher erosion rate could be related to the skill of the surgeon and the full thickness dissection of the vaginal mucosa in the SIM procedure. Additionally, after healing, the mesh material itself could account for the increased mesh exposure rate. The mesh used in the SIM procedure is a low-density (25.5 g/m²) [27], type 1 polypropylene graft (IntePro Lite, American Medical Systems, Minnetonka, MN, USA), which is only one-half the density of the mesh used in the TVM system. Moore et al [28] reported a 46% reduction in mesh exposure using the lightweight, type I polypropylene mesh. Lo et al [11] reported no significant difference in the mesh exposure rates comparing the anterior Elevate and Perigee plus SSF procedures. However, the follow-up time was only 1 year, and they did not mention whether the Perigee mesh they used was the light or heavyweight mesh.

Finally, there was no significant difference in postoperative VAS for pain between the TVM and SIM groups. Due to our modification of the Apogee mesh placement in the procedure, the vaginal mesh penetrated the bilateral SS ligaments in both groups. Initially, we assumed that the TVM system would cause more postoperative pain due to the skin penetration wounds. However, the result showed no difference between the groups. The patients complained more of postoperative soreness and pain in the buttock area rather than in the skin wound area, which could have been due to penetration of the SS ligament.

Limitations of this study include the fact that subjective outcomes using a standardized questionnaire to assess quality of life were lacking, and the retrospective nature of this study. The strengths of this study include the relatively large cohort number and the average 2-year follow-up time. In addition, the operations were performed by two experienced surgeons (KHH and FCC), who have both performed more than 100 vaginal mesh operations for POP, which exclude individual heterogeneity.

Conclusion

The use of both the anterior/apical and posterior/apical Elevate repair systems (SIM systems) resulted in similar anatomical restoration outcomes, but higher postoperative SUI, and lower mesh exposure rates at an average follow-up time of 2 years when compared with the Perigee and Apogee systems (TVM systems). The

occurrence of postoperative pain was equivalent in both groups. There was no posterior compartment recurrence in both groups. The overall cure rate in either group was satisfactory.

Conflicts of interest

The authors have no conflicts of interest relevant to this article.

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References

- [1] Lowenstein E, Ottesen B, Gimbel H. Incidence and lifetime risk of pelvic organ prolapse surgery in Denmark from 1977 to 2009. *Int Urogynecol J* 2015;26:49–55.
- [2] Olsen AL, Smith VJ, Bergstrom JO, Colling JC, Clark AL. Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence. *Obstet Gynecol* 1997;89:501–6.
- [3] Maher C, Feiner B, Baessler K, Schmid C. Surgical management of pelvic organ prolapse in women. *Cochrane Database Syst Rev* 2013;4:CD004014.
- [4] Carramao S, Auge AP, Pacetta AM, Duarte E, Ayrosa P, Lemos NL, et al. A randomized comparison of two vaginal procedures for the treatment of uterine prolapse using polypropylene mesh: hysteropexy versus hysterectomy. *Rev Col Bras Cir* 2009;36:65–72.
- [5] FDA. Safety Communication: UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse. 2011. <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm>.
- [6] Su TH, Lau HH, Huang WC, Hsieh CH, Chang RC, Su CH. Single-incision mesh repair versus traditional native tissue repair for pelvic organ prolapse: results of a cohort study. *Int Urogynecol J* 2014;25:901–8.
- [7] Rapp DE, King AB, Rowe B, Wolters JP. Comprehensive evaluation of anterior elevate system for the treatment of anterior and apical pelvic floor descent: 2-year follow-up. *J Urol* 2014;191:389–94.
- [8] Lukban JC, Roovers JP, Vandrie DM, Erickson T, Zylstra S, Patel MP, et al. Single-incision apical and posterior mesh repair: 1-year prospective outcomes. *Int Urogynecol J* 2012;23:1413–9.
- [9] Long CY, Hsu CS, Jang MY, Liu CM, Chiang PH, Tsai EM. Comparison of clinical outcome and urodynamic findings using “Perigee and/or Apogee” versus “Prolift anterior and/or posterior” system devices for the treatment of pelvic organ prolapse. *Int Urogynecol J* 2011;22:233–9.
- [10] Lo TS, Ashok K. Combined anterior trans-obturator mesh and sacrospinous ligament fixation in women with severe prolapse—a case series of 30 months’ follow-up. *Int Urogynecol J* 2011;22:299–306.
- [11] Lo TS, Bt Karim N, Cortes EF, Wu PY, Lin YH, Tan YL. Comparison between Elevate anterior/apical system and Perigee system in pelvic organ prolapse surgery: clinical and sonographic outcomes. *Int Urogynecol J* 2015;26:391–400.
- [12] Bump RC, Mattiasson A, Bø K, Brubaker LP, DeLancey JOL, Klarskov P, et al. The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. *Am J Obstet Gynecol* 1996;175:10–7.
- [13] Erickson TB. Innovations in the treatment of vaginal prolapse. *OBG management* 2006;18(Suppl):S5–8.
- [14] Huang KH, Huang LY, Chu LC, Chuang FC, Wu MP, Kung FT. Evaluation of the single-incision Elevate system to treat pelvic organ prolapse: follow-up from 15 to 45 months. *Int Urogynecol J* 2015;26:1341–6.
- [15] Chu LC, Chuang FC, Kung FT, Huang KH. Comparison of short-term outcomes following pelvic reconstruction with Perigee and Apogee systems: hysterectomy or not? *Int Urogynecol J* 2012;23:79–84.
- [16] Withagen MI, Vierhout ME, Milani AL. Does trocar-guided tension-free vaginal mesh (Prolift) repair provoke prolapse of the unaffected compartments? *Int Urogynecol J* 2010;21:271–8.
- [17] Kasturi S, Diaz SI, McDermott CD, Woodman PJ, Bump RC, Terry CL, et al. De novo stress urinary incontinence after negative prolapse reduction stress testing for total vaginal mesh procedures: incidence and risk factors. *Am J Obstet Gynecol* 2011;205:487.e1–4.
- [18] Hannestad YS, Rortveit G, Sandvik H, Hunskaar S. A community-based epidemiological survey of female urinary incontinence: the Norwegian EPI-NCOT Study. *J Clin Epidemiol* 2000;53:1150–7.
- [19] Stothers L, Friedman B. Risk factors for the development of stress urinary incontinence in women. *Curr Urol Rep* 2011;12:363–9.
- [20] Chang K-M, Hsieh C-H, Chiang H-S, Lee T-S. Risk factors for urinary incontinence among women aged 60 or over with hypertension in Taiwan. *Taiwan J Obstet Gynecol* 2014;53:183–6.
- [21] Marschalek J, Trofaiar M-L, Yerlikaya G, Hanzal E, Koelbl H, Ott J, et al. Anatomic outcomes after pelvic-organ-prolapse surgery—comparing uterine preservation with hysterectomy. *Eur J Obstet Gynecol Reprod Biol* 2014;183:33–6.

- [22] Altman D, Granath F, Chattingius S, Falconer C. Hysterectomy and risk of stress-urinary-incontinence surgery: nationwide cohort study. *The Lancet* 2007;370:1494–9.
- [23] Kudish BI, Shveiky D, Gutman RE, Jacoby V, Sokol AI, Rodabough R, et al. Hysterectomy and urinary incontinence in postmenopausal women. *Int Urogynecol J* 2014;25:1523–31.
- [24] Hsieh CH, Chang WC, Lin TY, Su TH, Li YT, Kuo TC, et al. Long-term effect of hysterectomy on urinary incontinence in Taiwan. *Taiwan J Obstet Gynecol* 2011;50:326–30.
- [25] Haylen BT, Freeman RM, Swift SE, Cosson M, Davila GW, Deprest J, et al. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint terminology and classification of the complications related directly to the insertion of prostheses (meshes, implants, tapes) and grafts in female pelvic floor surgery. *Int Urogynecol J* 2011;22:3–15.
- [26] Kirsner RS, Eaglstein WH. The wound healing process. *Dermatol Clin* 1993;11: 629–40.
- [27] Lukban JC, Beyer RD, Moore RD. Incidence of extrusion following type I polypropylene mesh kit repairs in the correction of pelvic organ prolapse. *Obstet Gynecol Int* 2012;2012:354897.
- [28] Moore RD, Lukban JC. Comparison of vaginal mesh extrusion rates between a lightweight type I polypropylene mesh versus heavier mesh in the treatment of pelvic organ prolapse. *Int Urogynecol J* 2012;23:1379–86.