UROGYNECOLOGY

# Laparoscopic sacral colpopexy versus total vaginal mesh for vaginal vault prolapse: a randomized trial

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**OBJECTIVE:** To compare the laparoscopic sacral colpopexy and total vaginal mesh for vaginal vault prolapse.

**STUDY DESIGN:** Women with symptomatic stage ≥2 vault prolapse were randomly allocated the laparoscopic sacral colpopexy (53) or total vaginal mesh (55). Primary outcome measures were objective success rates at pelvic organ prolapse quantification sites individually and collectively. Secondary outcome measures included perioperative outcomes, patient satisfaction, quality of life outcomes, complications, and reoperations.

**RESULTS:** The laparoscopic sacral colpopexy group had a longer operating time, reduced inpatient days, and quicker return to activities of daily living as compared with the total vaginal mesh group. At the 2-year review, the total objective success rate at all vaginal sites was 41 of 53 (77%) for laparoscopic sacral colpopexy as compared with 23 of 55 (43%) in total vaginal mesh ($P < .001$). Reoperation rate was significantly higher after the vaginal mesh surgery 12 of 55 (22%) as compared with laparoscopic sacral colpopexy 3 of 53 (5%) ($P = .006$).

**CONCLUSION:** At 2 years, the laparoscopic sacral colpopexy had a higher satisfaction rate and objective success rate than the total vaginal mesh with lower perioperative morbidity and reoperation rate.

**Key words:** laparoscopic sacral colpopexy, vaginal mesh repair, vaginal vault prolapse

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The sacral colpopexy has long been regarded as the gold standard procedure for the management of apical vaginal prolapse[1-4] with a superior anatomic outcome as compared with the vaginal sacrospinous colpopexy. The longer operating time, hospitalization, and recovery time have led many clinicians to perform this procedure laparoscopically to reduce length of admission and recovery time associated with the laparotomy. On initial case series the laparoscopic sacral colpopexy (LSC) seems safe and effective.[5-8] After the success of vaginal suburethral tapes in continence surgery vaginal mesh kits have been developed for the treatment of vaginal prolapse. The total vaginal mesh (TVM) kit (Gynecare Prolift Ethicon, Somerville, NJ) was launched in 2004 for the management of apical vaginal prolapse and became available in the Australian market in 2005 with acceptable success rates and complications reported in case series.[9,10] Despite the LSC and TVM being available for more than 5 years, both procedures remain untested under the rigors of a randomized controlled trial. The aim of this study is to compare the LSC and the TVM in the management of vaginal vault prolapse.

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## Materials and Methods

From the end of 2005, consecutive women referred to Wesley, Royal Brisbane's and Mater tertiary referral Urogynaecology unit with symptomatic stage 2 or greater (point C ≥ −1 pelvic organ prolapse quantification [POP-Q]) vaginal vault prolapse were eligible for inclusion. Recruitment was completed at the end of 2007. Exclusion criteria included those younger than 18 years of age, inability to comprehend questionnaires, to give informed consent or to return for review, vault prolapse < stage 2, unable to undergo general anesthesia, body mass index (BMI) >35, ≥5 previous laparotomies, prior sacral colpopexy, or vaginal mesh prolapse procedure or vaginal length less than 6 cm. Before surgery women were examined (POP-Q) by consultant and fellows in Urogynaecology, completed patient administered validated pelvic floor and quality of life questionnaires (Australian Pelvic Floor Questionnaire [APFQ][11] and Kings College Pelvic Organ Prolapse quality of life [P-QoL][12]) and underwent multichannel urodynamics with bladder filling to maximum of 500 mL, without and with prolapse reduction. Prolapse was reduced using sponge-holding forceps at the vault. Women without symptoms of urinary stress incontinence (USI) and with positive stress test with or without prolapse reduction were consid-

ered as having occult stress urinary incontinence (SUI).

Those who were eligible and agreed to participation completed written consent forms and were enrolled by consultant and Urogynaecology fellows. After completion of study consent, research support staff were telephoned and allocation to the laparoscopic or vaginal surgery group from randomization list that were computer generated by the study statistician, stratified for urodynamic stress incontinence (SUI and occult USI) with full allocation concealment, was completed.

The LSC was performed identically to our open sacral colpopexy reported in 2004[3] with the exception of the entry technique in which a nondisposable Hassan entry with 3 additional trocars (Applied Medical, Rancho Sante Margarita, CA) was used. The retroperitoneum was opened using monopolar diathermy from sacral promontory to vault with the incision just medial to the uterosacral ligament. With an Apple vaginal probe (Applemed, Marlborough, MA) in position, the bladder was mobilized from the vagina to the level of the trigone creating the vesicovaginal space anteriorly and the bowel was mobilized 7-8 cm along the posterior vagina to create the rectovaginal space. A self-styled Y-shaped piece monofilament polypropylene large pore mesh (Prolene 15 × 15cm; Ethicon) was secured to the anterior and posterior vagina with two to three 2.0 polydiaxone sutures (PDS Ethicon; Ethicon) and to the sacral promontory using the Hernia tacker (ProTack 5 mm; Tyco Healthcare, Mansfield, MA). The mesh was crafted to suit the individual with the anterior leaf typically 7-8 cm long and 4.5 cm wide. The posterior leaf was 4.5 cm wide and 22 cm long. The retropertioneal space was closed continuous 2.0 PDS suture. All women with SUI or occult SUI underwent colposuspension and those with significant anterior compartment prolapse without SUI underwent paravaginal repair. Those with low posterior compartment prolapse underwent a distal midline fascial plication as previously described at the end of the surgery.

In the TVM procedure, a Total Prolift (Gynecare, Ethicon) was performed as described by Fatton et al[9] with the addition of a tacking 2.0 polyglactin absorbable suture (Vicryl; Ethicon) at the distal anterior and posterior tails to the vaginal fascia without breaching the mucosa to minimize the possibility of the mesh retracting proximally or folding in the early postoperative days. In the rare case of minimal anterior or posterior compartment prolapse, the anterior or posterior leaf of the total prolift was removed and this decision was made intraoperatively. An inside-out transvaginal obturator suburethral tape (TVT-O; Gynecare, Ethicon) was performed in all women with USI or occult stress incontinence. Surgery was performed by C.M. (consultant Urogynaecologist) or by E.D. (Urogynaecology fellow) with C.M. assisting and both authors had completed at least 30 laparoscopic and vaginal prolapse mesh surgical procedures before commencing the study. Before commencing vaginal mesh surgery, C.M. underwent training in Lille, France, with the developers of the TVM technique. Before the trial commencing LSC and vaginal mesh procedures were used for the management of vaginal vault prolapse.

Perioperative parameters were defined as follows: operating time was from knife to skin to cessation of cystoscopy. Intraoperative blood loss was defined in milliliters by the consultant anesthetist. All patients had the indwelling catheter removed at 0600 on day 1 and completed a 24-hour trial of void. Patients were discharged after a successful trial of void or successful teaching of clean intermittent self-catheterization (CISC) and not requiring narcotics injection in the last 12 hours. Catheters days were defined as days indwelling catheter or CISC was used. Admission days equaled number of nights in hospital at midnight. Pain score at 1 month was recorded on a visual analogue scale of 0-10 (0 nil; 10 worst). Return to activities of daily living was defined as days to return to driving, preparing meals, and shopping. Mesh contraction has previously been defined.[13] All other definitions complied with the ICS terminology[14] and urodynamic voiding dysfunction was defined as maximum urinary flow rate $<15$ mL/sec on 2 occasions with a voided volume $>150$ mL and residual urine $>100$ mL.[15]

The 6-week examination and review was performed by the surgeon with all study data and future visits (6 months and annually thereafter) completed by blinded coauthors (Urogynaecology fellows × 2 and research nurse) who remained unaware of group allocation. Women with problems were referred by the reviewers to our clinic for management. The complete presurgical evaluation was repeated at all reviews, excluding multichannel urodynamic analysis that was performed only at 6 months. Self-assessed patient satisfaction (circle a score that describes your satisfaction with surgery) was completed on a visual analogue scale of 0-100 with 0 being lowest as previously described.[15]

Given a 76% 2-year objective success rate for open sacral colpopexy[3] and 92% with vaginal mesh Prolift,[9] the sample size required to detect a 30% difference in success rates with a power of 80% and alpha = .05 was 47 per group. To allow for drop of 15% and to ensure an adequately powered study 110 were recruited. The aim of the study was to compare the LSC and TVM in the management of vaginal vault prolapse at 2 and 5 years with the null hypothesis being that no significant differences existed between the 2 surgical procedures.

Primary outcome measures were objective success rates at POP-Q sites Aa, Ba, C, Bp, and Ap defined as less than $-1$ cm individually and as a total. Secondary outcome measures included perioperative outcomes, patient satisfaction, quality of life outcomes, complications, and reoperations.

The study protocol was approved by the institutional review boards at the Royal Women's (2004067), Wesley (200445), and Mater hospitals (776A) and written informed consent was obtained from all participants on enrollment. The study has been registered at ANZCTR clinical trials registry after the enrollment of patients had commenced (ACTRN12609000119291).

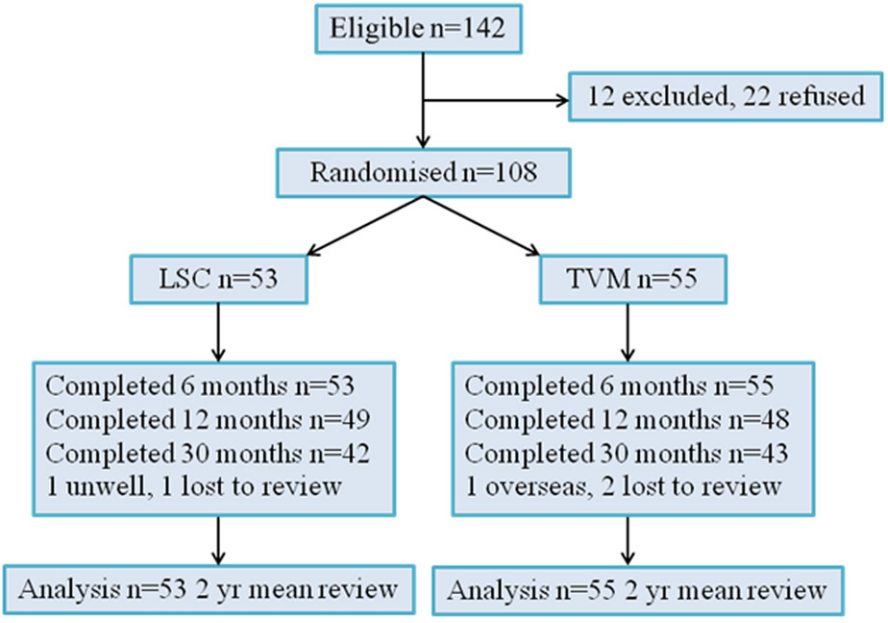
Frequency and percentages were used to describe categorical variables, Fisher's

exact test used to compare treatment groups, and logistic regression used to estimate odds ratios (ORs), and associated 95% confidence intervals (95% CIs). Matched analyses for pre- and postconsistency for urodynamic characteristics used McNemar test. Means and standard deviations (SDs) were used to describe approximately normally distributed continuous data. Analysis of covariance (ANCOVA) was used to compare treatment groups at 2 years postintervention adjusting for preintervention values and to estimate mean differences between treatment groups and associated (95% CI). Medians and range (minimum, maximum values) were used to describe non-normally distributed continuous data, Wilcoxon rank sum test used to compare treatment groups and Student *t* test to estimate mean differences and associated (95% CI). Paired *t* tests were used for differences between pre- and postmeasurements. All analyses were undertaken using Stata version 10.0 (StataCorp, College Station, TX) and SAS version 9.1 (SAS Institute Inc, Cary, NC); and $\alpha = .05$ defined statistical significance for all tests. Data was analyzed on an intention-to-treat basis.

## RESULTS

The Figure details patients' progress through the study with 108 women of 142 potentially eligible, consenting to randomization and participation with 53 allocated LSC and 55 vaginal mesh repair. All completed at least 6 months follow-up. The randomization process was adequate with no differences between the 2 groups in demographics and preoperative variables as seen in Table 1. Wilcoxon test indicate no significant difference between treatment groups for preoperative POP-Q measurements except for perineal body ($P = .046$), but this mean difference of 0.10 cm was not clinically significant. Perioperative outcomes indicate that the LSC surgery took approximately twice as long to perform as the TVM but was associated with a significantly lower blood loss, shorter hospitalization and quicker return to activities of daily living (Table 2).

FIGURE
**Randomized trial flow diagram**




The randomized trial flow diagram including total sample size, enrollment, intervention allocation, follow-up, and analysis.

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Concomitant surgery in the laparoscopic group included, 27 low posterior vaginal repair, 21 colposuspension, 27 paravaginal repair, 11 adhesion lysis longer than 45 minutes, and 1 right oopherectomy for benign ovarian cyst. In the vaginal group (55), 53 total mesh kits were used with 1 woman having the anterior leaf and 1 posterior leaf removed because of limited vaginal prolapse at that site and 23 undergoing TVT-Os.

At mean 2-year review objective assessment demonstrated there was a significant reduction in extent of prolapse at POP-Q sites, including Aa, Ba, C, Bp, and Ap in both groups as compared with preoperative assessment. Total vaginal length (TVL) was unchanged in the laparoscopic arm and was significantly shorter in the TVM group postoperatively. Postoperative comparisons between the groups revealed the laparoscopic arm had a significantly superior performance at POP-Q sites Aa, Ba, C, Bp, Ap, and TVL as compared with the TVM (Table 3). The objective success rate (POP-Q stage 0 or 1 prolapse at all vaginal sites) was 41 of 53 (77%) in the laparoscopic arm as compared with 23 of 55 (43%) in the vaginal mesh group ($P < .001$; OR, 4.75; 95% CI, 2.06–10.98). One woman had symptomatic prolapse (2%) in the LSC group and 4 (7%) in the vaginal mesh group ($P = .18$). Mean patient satisfaction (0-100) was significantly higher in the LSC group $87 \pm 21$ as compared with $79 \pm 20$ in the vaginal mesh group ($P = .002$ mean difference 8.09 (95% CI, 0.20–15.98).

There was no difference in preoperative scores for any urodynamic parameter between the groups. There was no difference in rates of SUI at 6-month review between groups ($P = .08$) and no differences between 6-month review and preoperative scores for flow rate, voiding dysfunction, bladder capacity, and detrusor overactivity. There was a small though significant increase in postoperative maximum urethral closure pressure (MUCP) as compared with baseline in both groups (Table 4).

There was a significant improvement in symptom severity and quality of life scores using patient administered validated questionnaires APFQ and P-QoL in both the LSC and TVM procedures

**TABLE 1**
**Compare demographic and preoperative risk factors between the 2 groups**

| Demographics | LSC | | | TVM (total Prolift) | | | |
|---|---|---|---|---|---|---|---|
| **Review** | **n** | **Mean** | **(SD) or %** | **n** | **Mean** | **(SD) or %** | ***P* value** |
| Age, y | 53 | 63 | (8.1) | 55 | 63 | 8.8 | .85 |
| BMI | 50 | 28 | (3.3) | 54 | 28 | (4.2) | .2 |
| Parity median (range) | 53 | 2 | 0–6 | 55 | 2 | 0–7 | .78 |
| Menopausal | 53 | 45 | 85 | 55 | 44 | 80 | .62 |
| Smokers | 53 | 4 | 8 | 55 | 1 | 2 | .36 |
| White nationality | 53 | 52 | 98 | 55 | 53 | 96 | .75 |
| Household income ($25–50k) | 53 | 35 | 66 | 55 | 34 | 62 | .53 |
| Educational (secondary school) | 53 | 32 | 60 | 55 | 25 | 45 | .27 |
| Employment (home duties) | 53 | 36 | 68 | 55 | 34 | 62 | .86 |
| Constipation | 53 | 13 | 24 | 55 | 16 | 29 | .27 |
| Chronic chest pathology | 53 | 4 | 8 | 55 | 1 | 2 | .36 |
| Sex activity | 53 | 20 | 38 | 55 | 18 | 33 | .42 |
| Dyspareunia | 20 | 3 | 15 | 18 | 2 | 11 | .56 |
| TAH | 53 | 34 | 64 | 55 | 29 | 53 | .25 |
| Prior POP/continence sex | 53 | 37 | 70 | 55 | 35 | 64 | .56 |
| Prior pelvic floor surgery/patient (range) | | 1.2 | 0–6 | | 1.0 | 0.7 | .78 |

Prolift; Gynecare Ethicon, Somerville, NJ.
*BMI*, body mass index; *LSC*, laparoscopic sacral colpopexy; *POP*, pelvic organ prolapse; *TAH*, total abdominal hysterectmy; *TVM*, total vaginal mesh.
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postoperatively as compared with preoperatively. There was no significant difference in the pre- and postoperative quality of life changes between the groups (Table 5).

Perioperative complications in the laparoscopic group included 1 cystotomy and small bowel enterotomy, both of which were repaired intraoperatively without sequelae. After the enterotomy, the LSC was abandoned and converted to a TVM procedure and under intention-to-treat guidelines remained in LSC arm analysis. One patient in each group was transfused perioperatively and 5 urinary tract infections were recorded, 2 in LSC group and 3 in vaginal group. One woman in vaginal group was readmitted with an infected pelvic hematoma that settled with intravenous antibiotics. One woman (2%) in LSC and 7 (13%) in the vaginal group had vaginal mesh erosions ($P = .07$). All women had vaginal estrogen therapy administered and 2 in the

**TABLE 2**
**Perioperative details**

| | LSC | | | TVM | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Variable** | **n** | **Median** | **[min, max]** | **n** | **Median** | **[min, max]** | ***P* value[a]** | **Mean difference** | **(95% CI)[b]** |
| Operating time, min | 53 | 97 | [36, 280] | 55 | 50 | [30, 96] | < .001 | 52.0 | (41.4–62.6) |
| Blood loss, mL | 53 | 100 | [20, 300] | 55 | 150 | [21, 500] | .004 | −32.0 | (−59.4 to −4.5) |
| In-patient stay, d | 53 | 2 | [2, 10] | 55 | 3 | [2, 6] | .01 | −0.52 | (−0.93 to −0.10) |
| Catheterization, d | 53 | 1 | [1, 42] | 55 | 2 | [1, 21] | .44 | 0.22 | (−1.87 to 2.31) |
| Pain score | 53 | 0 | [0, 80] | 54 | 0 | [0, 50] | .10 | 0.20 | (−5.06 to 5.45) |
| Return to normal activity, d | 53 | 21 | [7, 50] | 54 | 21 | [5, 63] | <.001 | −5.34 | (−8.36 to −2.32) |

*CI*, confidence interval; *LSC*, laparoscopic sacral colpopexy; *TVM*, total vaginal mesh.
[a] Calculated using Wilcoxon rank sum test; [b] Determined using Student *t* test.
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**TABLE 3**
**Pre- and postoperative POP-Q site measurements (cm) at mean 2 years**

| | LSC (n = 53) | | | | | TVM (n = 55) | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Variable | Pre mean | (SD) | Post mean | (SD) | *P* value[a] | Pre mean | (SD) | Post mean | (SD) | *P* value[a] | *P* value between post groups[b] | Mean difference (TVM-LSC) | (95% CI) |
| Aa | 1.00 | (1.89) | −2.09 | (0.56) | .001 | 0.95 | (1.86) | −1.44 | (1.24) | .014 | .004 | −0.65 | (−1.00 to −0.30) |
| Ba | 1.41 | (1.73) | −2.17 | (0.51) | < .001 | 1.18 | (1.71) | −1.50 | (1.19) | < .001 | .001 | −0.53 | (−0.82 to −0.24) |
| C | 2.58 | (3.13) | −7.48 | (2.62) | < .001 | 2.82 | (3.39) | −6.11 | (2.72) | < .001 | .001 | −1.33 | (−2.35 to −0.32) |
| Gh | 3.06 | (0.31) | 3.00 | (0.00) | .18 | 2.98 | (0.13) | 3.04 | (0.19) | .08 | .16 | −0.04 | (−0.09 to 0.01) |
| Pb | 2.94 | (0.31) | 3.02 | (0.24) | .16 | 3.04 | (0.19) | 3.00 | (0.19) | .41 | .65 | 0.02 | (−0.06 to 0.10) |
| TVL | 8.94 | (0.31) | 8.83 | (0.55) | .11 | 9.00 | (0.19) | 7.81 | (1.40) | < .001 | < .001 | 1.01 | (0.61–1.42) |
| Ap | −0.31 | (1.77) | −2.32 | (0.61) | < .001 | 0.04 | (1.72) | −1.65 | (1.05) | < .001 | .001 | −0.68 | (−1.00 to −0.35) |
| Bp | 0.41 | (1.64) | −2.30 | (0.64) | < .001 | 0.32 | (1.72) | −1.63 | (1.05) | < .001 | .006 | −0.68 | (−0.97 to −0.40) |

*CI*, confidence interval; *LSC*, laparoscopic sacral colpopexy; *POP-Q*, pelvic organ prolapse quantification; *TVL*, total vaginal length; *TVM*, total vaginal mesh.

[a] Based on Wilcoxon signed rank test for nonparametric data; [b] Based on analysis of covariance correcting for the preoperative value.

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vaginal group who were asymptomatic elected not to have the mesh erosion corrected.

Indications for reoperations are detailed in Table 6. One woman in the LSC group underwent a nephrectomy 3 months postoperatively for an intraoperatively detected nonfunction atrophic left kidney. One woman in the vaginal group underwent bowel resection for diverticulitis 12 months postoperatively. These 2 women are not included in the reoperation analysis as the indications for surgery are not related to the index prolapse repair. Three (5%) women underwent 3 reoperations (1 TVT, 1 trocar hernia, 1 mesh erosion) in the laparoscopic group as compared with 12 (22%) women (4 excision mesh contracture, 3 with associated mesh erosion, 3 suburethral tapes, 3 LSC, and 2 oversowing mesh erosion with excision exposed mesh) underwent 15 reoperations in the vaginal group ($P = .006$; OR, 4.65; 95% CI, 1.23–17.57).

## Comment

The results indicate that both procedures had acceptable perioperative outcomes with the longer operating time being a disadvantage of the LSC that was offset by small but statistically significant reduction in blood loss, inpatient stay, catheter days, and return to activities of daily living in the LSC group as compared with the TVM group.

At mean 2 year review, the anatomic outcome saw a significant reduction in Aa, Ba, C, Ap, and Bp in both groups as compared with the preoperative assessment. Postoperatively the TVL was significantly reduced in the vaginal group with no change identified in the LSC group and a similar finding was reported in a recent evaluation retrospectively comparing Prolift and sacral colpopexy.[16] The mean difference between the groups was significantly superior at Aa, Ba, C, Ap, and Bp and TVL significantly longer in the LSC group as compared with vaginal mesh

**TABLE 4**
**Urodynamic characteristics of patients before the operation and at the 6-month review for the 2 treatment groups**

| | LSC | | | | | | TVM | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Preoperation | | | 6-mo review | | | Preoperation | | | 6-mo review | | |
| Characteristic | n | | (%) | n | | (%) | n | | (%) | n | | (%) |
| Voiding dysfunction | 3 | | (6) | 5 | | (10) | 9 | | (17) | 4 | | (8) |
| OAB | 18 | | (35) | 20 | | (41) | 19 | | (37) | 14 | | (27) |
| SUI | 20 | | (38) | 7 | | (16) | 23 | | (43) | 14 | | (33) |
| | n | median | [min, max] | n | median | [min, max] | n | median | [min, max] | n | median | [min, max] |
| Bladder capacity, mL | 52 | 500 | [259, 503] | 51 | 486 | [192, 502] | 55 | 500 | [241, 500] | 52 | 500 | [196, 500] |
| Flow rate, mL | 51 | 13 | [2, 67] | 48 | 13 | [3, 47] | 54 | 15 | [0, 47] | 49 | 13 | [0, 55] |
| MUCP | 51 | 21 | [2, 100] | 51 | 24 | [0, 64] | 55 | 24 | [1, 81] | 52 | 28 | [5, 118] |

*LSC*, laparoscopic sacral colpopexy; *MUCP*, maximum urethral closure pressure; *OAB*, overactive bladder; *SUI*, stress urinary incontinence; *TVM*, total vaginal mesh.

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**TABLE 5**
**Quality of life outcomes preintervention and 2 years postintervention and between the 2 groups**

| | LSC (n = 53) | | | | TVM (n = 55) | | | | *P* value | Mean | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Variable | Pre mean | (SD) | Decrease from pre to post, % | *P* value | Pre mean | (SD) | Decrease from pre to post, % | *P* value | between post groups[a] | difference (TVM-LSC) | (95% CI)[a] |
| APFQ | | | | | | | | | | | |
| Bladder | 3.4 | (1.8) | 47 | < .001 | 3.2 | (1.7) | 44 | < .001 | .59 | −0.13 | (−0.61 to 0.35) |
| Bowel | 2.7 | (1.6) | 22 | .007 | 2.0 | (1.4) | 5 | .92 | .67 | 0.10 | (−0.35 to 0.54) |
| Prolapse | 5.4 | (2.2) | 91 | < .001 | 5.3 | (2.0) | 87 | < .001 | .49 | −0.16 | (−0.62 to 0.30) |
| Sex | 1.3 | (2.1) | 31 | .14 | 1.0 | (1.7) | 0 | .95 | .76 | −0.09 | (−0.64 to 0.47) |
| Total | 12.7 | (4.9) | 59 | < .001 | 11.4 | (4.1) | 53 | < .001 | .70 | −0.28 | (−1.67 to 1.11) |
| P-QoL | | | | | | | | | | | |
| General health | 29.2 | (23.9) | 13 | .15 | 24.5 | (17.2) | −19 | .049 | .18 | −3.61 | (−8.85 to 1.62) |
| Prolapse impact | 71.1 | (28.5) | 82 | < .001 | 68.5 | (27.8) | 77 | < .001 | .44 | −3.58 | (−12.67 to 5.51) |
| Role limitation | 42.5 | (34.8) | 87 | < .001 | 33.3 | (32.1) | 74 | < .001 | .32 | −3.20 | (−9.44 to 3.05) |
| Physical limitation | 36.5 | (31.0) | 87 | < .001 | 31.8 | (31.4) | 74 | < .001 | .25 | −3.54 | (−9.58 to 2.49) |
| Social limitation | 18.4 | (27.5) | 86 | < .001 | 13.7 | (19.0) | 91 | < .001 | .32 | 1.28 | (−1.24 to 3.80) |
| Relationships | 35.8 | (39.1) | 75 | < .001 | 27.5 | (36.2) | 77 | < .001 | .51 | 2.72 | (−5.40 to 10.84) |
| Emotional score | 32.3 | (33.2) | 85 | < .001 | 36.4 | (32.2) | 82 | < .001 | .61 | −1.42 | (−6.82 to 3.98) |
| Sleep energy | 42.5 | (31.3) | 60 | < .001 | 40.7 | (28.9) | 71 | < .001 | .27 | 4.71 | (−3.69 to 13.11) |
| Severity score | 36.2 | (22.4) | 80 | < .001 | 31.5 | (22.2) | 75 | < .001 | .82 | −0.51 | (−4.98 to 3.95) |

*APFQ*, Australian Pelvic Floor Questionnaire; *CI*, confidence interval; *LSC*, laparoscopic sacral colpopexy; *P-QoL*, pelvic organ prolapse quality of life; *TVM*, total vaginal mesh.

[a] Based on analysis of covariance correcting for the preoperative value.

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group. The overall 77% objective success rate of the LSC is almost identical to the 76% outcome for open sacral colpopexy that we reported in a prior randomization control trial (RCT) comparing open sacral colpopexy and vaginal sacrospinous colpopexy.[3] The 43% objective success rate reported in the vaginal mesh group is lower than that previously reported in some vaginal mesh series.[9,17-19] This difference might be explained by this evaluation being the longest follow-up reported for TVM (Medline search terms "vaginal mesh," "total vaginal mesh," or "total Prolift," years 2004-August 2010), the only evaluation under the auspices of a RCT with blinded nonsurgeon reviewers and the only evaluation limited to only post-hysterectomy prolapse.

The low rate of postoperative symptomatic prolapse is testament to the success of both surgeries with only 1 in LSC and 4 in vaginal mesh group having symptomatic prolapse. Interestingly, the patient satisfaction score on self-administered VAS was significantly higher in the LSC group as compared with vaginal mesh group but no significant differences were able to be detected in quality of life analysis between the groups. The most obvious differences between the groups that may account for the higher satisfaction in the LSC group were the 4 times higher reoperation rate in the vaginal mesh group as compared with LSC arm as listed in Table 6. Mesh contracture and further prolapse and continence surgery accounted for the bulk of the reoperations in the vaginal group with only 2 procedures being performed for mesh erosions only. Total rate of reoperations in the prolapse literature are

**TABLE 6**
**Compare indications for reoperation in the groups**

| Indications | LSC (53) n (%) | TVM (55) n (%) | *P* value |
|---|---|---|---|
| Mesh erosions | 1 (2) | 5 (9) | .11 |
| Mesh contractions | 0 | 4 (7) | .05 |
| TVT-O | 1 (2) | 3 (5) | .36 |
| POP surgery | 0 | 3 (5) | .11 |
| Trocar hernia | 1 (2) | 0 | .49 |
| L nephrectomy | 1 (2) | 0 | .49 |
| Bowel resection | 0 | 1 (2) | .49 |
| Surgery related primary surgery | 3 (5) | 12 (22) | .006 |

*LSC*, laparoscopic sacral colpopexy; *POP*, pelvic organ prolapse; *TVM*, total vaginal mesh; *TVT-O*, transvaginal obturator suburethral tape.

*Maher. Laparoscopic sacral colpopexy vs vaginal mesh repair. Am J Obstet Gynecol 2011.*

generally poorly reported but the individual rates of mesh erosions, contracture, and reoperation for continence and prolapse individually are well within accepted reporting levels.

The strengths of this study include adequate sample size in a prospective randomized setting, a mean 2-year follow-up, with blinded nonsurgical reviewers. Potential weaknesses include a single site study with only 2 surgeons (consultant and fellow urogynaecology) that may limit the generalizability of the findings. Furthermore, the surgical expertise may not have been equal with vaginal surgery being performed twice as frequently as laparoscopic surgery in our institution and the longer learning curve of LSC. This potential limitation was minimized by all surgeons having to perform 30 LSC and vaginal mesh procedures before operating in the study to limit any potential impact of the learning curve on outcomes. The learning curve for LSC and TVM is significant with the safe dissection to create the vesicovaginal and rectovaginal spaces being vital in both procedures. Other rate limiting factors on the learning curve include laparoscopic suturing in the LSC group and safe introduction of blind trocars through obturator and gluteal spaces in the vaginal group. Finally, given that 1 surgery was laparoscopic and 1 vaginal, the subjects were not and could not be blinded to their allocation.

Despite these limitations, and both procedures being available for over 5 years, this study represents the sole RCT comparison between the LSC or TVM. Although the LSC took longer to perform, the advantages over the TVM included reduced blood loss, inpatient and catheter days, quicker return to activities of daily living, reduced anatomic prolapse, longer TVL, reduced reoperations rate, and greater patient satisfaction as compared with total vaginal mesh procedure. Further rigorous evaluation of both procedures is required. ■

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