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ORIGINAL ARTICLE

A prospective comparison of two commercial mesh kits in the management of anterior vaginal prolapse

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Abstract
Introduction and hypothesis Vaginal mesh kits are increasingly used in the management of pelvic organ prolapse. This study aimed to determine similarity of outcomes of the Anterior Prolift® with Perigee® systems for anterior compartment prolapse.
Methods Consecutive women undergoing Perigee® or Anterior Prolift® for symptomatic stage 2 or greater anterior vaginal prolapse were prospectively evaluated. Main outcome measures included objective and subjective success rates, perioperative outcomes, patient satisfaction, and complications.
Results One hundred and six women (Prolift, 52; Perigee, 54) completed questionnaires, and 91 (Prolift, 46; Perigee, 45) were examined postoperatively. At follow-up (Prolift: median, 11.0; range, 5–23 months; Perigee: median, 11.5; range, 6–23 months), objective success rates (Prolift, 89%; Perigee, 80%; p=0.23), subjective success rates (Prolift, 94%; Perigee, 96%; p=0.62), mean ± SD patient satisfaction (Prolift, 8.2±2.0; Perigee, 8.2±1.8; p=0.91), and complication rates did not differ significantly between the two groups.
Conclusions The Anterior Prolift® was found to not differ significantly from Perigee® at 11 months.

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Abbreviations

POP-Q	Pelvic organ prolapse quantification
RCT	Randomized controlled trial
POP	Pelvic organ prolapse
TVT-O	Tension-free vaginal tape–obturator
APFQ	Australian pelvic floor questionnaire
SD	Standard deviation
SUI	Stress urinary incontinence
UTI	Urinary tract infection
IDC	Indwelling catheter
CISC	Clean intermittent self-catheterizations
ADL	Activities of daily living

Introduction

Graft materials have been widely used in prolapse repair surgeries during the last decade [1]. Data from randomized controlled trials (RCTs) demonstrate a significant reduction in objective failure rates at 1- and 2-year follow-up durations using self-styled or Perigee® (American Medical Systems Inc., Minnetonka, MN, USA) polypropylene mesh implantation at the anterior vaginal compartment [2–4]. This finding was recently confirmed by the Cochrane review on the surgical management of pelvic organ prolapse (POP) in women [5]. However, available level one evidence of these superior outcomes is not as consistent for the widely utilized Anterior Prolift® system (Ethicon Women's Health and Urology, Somerville, NJ). While a recent large RCT confirmed superiority of the Prolift® mesh kit over anterior colporrhaphy in anatomical outcome, with no difference in quality-of-life measures and a higher complication rate [6], an earlier study has failed to demonstrate any advantage of the Prolift® mesh over no

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mesh repairs for a variety of anterior, posterior, and apical compartment prolapses [7], and a third trial has found it inferior to laparoscopic sacral colpopexy in managing post-hysterectomy vault prolapse [8]. These evidence suggest that the superior outcomes achieved by the Perigee mesh kit are not necessarily transferable to other mesh repair systems in the market. The aim of this study was to determine if the widely utilized Anterior Prolift® produced similar success rates to the Perigee® procedure in the management of anterior compartment prolapse.

Materials and methods

From January 2007, consecutive women undergoing prolapse surgery for symptomatic POP with points Aa and Ba equal to or greater than −1 cm according to the pelvic organ prolapse quantification system (POP-Q) were prospectively evaluated. Exclusion criteria included those with associated vault prolapse who were suitable and opted for laparoscopic sacral colpopexy (being our first-line intervention for vault prolapse as suggested by the latest published literature), prior mesh implantation for prolapse repair, and those refusing synthetic mesh implantation. Surgeries were undertaken at three different locations in Brisbane, Australia. Perigee® was performed only at Wesley campus and Anterior Prolift® at Royal Brisbane and Mater campuses, affording an opportunity to compare the two products. Patients self-allocated to the operating sites based on location, personal hospital preference, insurance status, and surgery availability. All surgeries were performed by two of the authors, i.e., CM (a consultant urogynecologist) and BF (a urogynecology fellow), according to the surgical technique that was previously described by Fatton et al. [9] for Prolift® and by Gauruder-Bermester et al. [10] for Perigee® with CM having undertaken more than 30 Anterior Prolift® and Perigee® procedures prior to the study's commencing and BF operating under CM's direct supervision. None of the surgeons had a greater experience in any particular procedure of the two techniques evaluated in this study. Women with an apical defect (either uterine prolapse or vault prolapse after hysterectomy) underwent a concomitant sacrospinous fixation with or without vaginal hysterectomy, depending on patient preference for uterine prolapse, and those with posterior compartment prolapse received a posterior fascial plication. Women with symptomatic or occult stress urinary incontinence (SUI) underwent TVT-O® (Ethicon Women's Health and Urology, Somerville, NJ).

Prospective data including demographics, medical and obstetric history, previous surgeries, preoperative POP-Q, and perioperative parameters were recorded. Postoperative patient evaluation was performed by a blinded reviewer at 6 weeks and 6-monthly thereafter and included pelvic examination using the POP-Q system [11], self-assessed patient satisfaction on a visual analog scale of 0–10 (with 0 being lowest) as previously described [12], and two additional questions: "would you undergo this surgery again?" and "would you recommend this surgery to a friend?" The Australian pelvic floor questionnaire (APFQ) [13], a validated symptoms and quality-of-life questionnaire, was used to compare postoperative scores of the bladder, bowel, prolapse, and sexual function domains between the two study groups (lower scores reflect better outcome), to determine subjective success rates and the prevalence of individual symptoms within each group.

Power calculations were performed prior to study commencement, based on previously published case series data of the two procedures [9, 10]. For a standard success rate of 90%, a sample size of 100 women (50 in each group) was required to establish equivalence within 15% with at least 80% power and one-sided significance level of 5%.

The primary outcome measure was objective success rate, both at the anterior vaginal wall (POP-Q sites Aa and Ba) and at the entire vagina (Aa, Ba, C, D, Ap, and Bp) defined as a value lower than −1 cm. Stage 2 prolapse, whether symptomatic or asymptomatic, was considered a failure. Secondary outcome measures included subjective success rate (the answer 'never' or 'less than once a week' to the question about prolapse sensation at the APFQ), patient satisfaction, quality of life scores, complication and re-operation rates.

Frequency and percentages were used to describe categorical variables. Means and standard deviations (SDs) were used to describe approximately normally distributed continuous data, while medians and range (minimum, maximum values) were used to describe non-parametric data. The Pearson chi-squared test was used to compare the two systems for categorical variables, and Student's t test or the Wilcoxon rank sum tests were used to compare continuous variables. Statistical significance was set at $p<0.05$ for all comparisons.

Since both the Anterior Prolift® and the Perigee® systems are used routinely and equally in our practice in women with stage 2 anterior compartment prolapse undergoing vaginal surgery, this study was designated a clinical audit by the chairperson of the Royal Brisbane & Women's Hospital Human Research Ethics Committee and exempted from a full ethics committee review. The study has been registered at ANZCTR clinical trials registry (ACTRN12609000112268).

Results

One hundred and six women (Prolift®, 52; Perigee®, 54) of 147 eligible consented and were included in the study.

Fifteen women (Prolift®, 6; Perigee®, 9) were unable to return after the 6-week review due to travel requirements of greater than 1,000 km but completed the validated questionnaires and satisfaction score. There were no significant differences between the two groups in demographics, previous surgeries for prolapse or incontinence, and distribution of POP-Q values at baseline as shown in Table 1. Concomitant surgical procedures including sacrospinous ligament suspension (with or without uterine preservation), vaginal hysterectomy, posterior colporrhaphy, and TVT-O® as well as perioperative outcomes are presented in Table 2 with no significant differences between the groups in any of the parameters.

At follow-up (Prolift: median, 11.0; range, 5–23 months; Perigee: median, 11.5; range, 6–23 months), objective success rates for Prolift® and Perigee® at the anterior vaginal wall were 89% (41/46) and 80% (36/45), p=0.23, and at all compartments, 78% (36/46) and 76% (34/45), respectively, p=0.76. Mean (SD) values of POP-Q points are summarized in Table 3. Subjective success rates were 94% (49/52) for Prolift® and 96% (52/54) for Perigee®, p=0.62, and mean ± SD patient satisfaction was 8.2±2.0 and 8.2±1.8, respectively, p=0.91. A similar proportion of women said they would undergo the surgery again (Prolift®, 89% (46/52); Perigee®, 93% (50/54), p=0.47) and recommend it to a friend (Prolift®, 90% (47/52); Perigee®, 91% (49/54), p=0.95). Mean postoperative scores for the validated questionnaire are presented in Table 3 with no significant difference in any of the domains (i.e., bladder, bowel, prolapse, and sexual function) and overall.

Peri- and postoperative complications were comparable between the groups (p=0.56) with three (6%) mesh erosions in the Prolift® group versus two (4%) after Perigee® and eight women (Prolift®, 3 (11%); Perigee®, 5 (16%)) experiencing de novo dyspareunia. In four of these women (Prolift®, 3; Perigee®, 1), mesh contraction, which was previously defined [14], was identified as the cause for their pain. Patients with postoperative dyspareunia underwent conservative management including topical estrogen therapy, pelvic floor physiotherapy, and vaginal dilators. None of these women required further intervention for persisting dyspareunia during the study period.

Urinary tract infection occurred in two patients in the Prolift® group and one patient in the Perigee® group, and one woman in each group required prolonged self-catheterization due to high post-void urinary residuals. Both these women had a urodynamically documented obstructed voiding pattern preoperatively. Overall, 75% and 78% respectively experienced no complications.

Five women in the Prolift® group (10%) versus three in the Perigee® group (6%) underwent a TVT-O® during the follow-up period due to persistent or de novo SUI. One patient who originally had a uterine preservation surgery with Prolift® later underwent vaginal hysterectomy for an isolated recurrent uterine prolapse, and two women in the Prolift® group required re-modeling of the posterior vaginal wall or perineum. One in each group (2%) underwent a surgical intervention of mesh erosion following failed conservative management with topical estrogen, and two women (one in each group) needed vaginal urethrolysis due to high post-void urine residuals. Overall, 87% had no re-operations, and there was no statistically significant difference between the groups in the number or indications for re-operations (p=0.33).

Discussion

The results of this prospective comparative trial demonstrate no significant difference between the anterior Prolift® procedure and Perigee® in objective success rate at the anterior vaginal compartment (89% versus 80%). Calculation of non-inferiority for anterior Prolift® against Perigee using these results for objective success rate indicates

Table 1 Baseline demographic and clinical data of the two groups

Variable	Prolift® (n=52)	Perigee® (n=54)	p value
Mean age ± SD (years)	60.1±9.6	60.1±8.9	0.99*
Median (range) parity	3 (1–7)	3 (1–8)	0.58*
Mean BMI ± SD (kg/m^2)	27.0±4.7	27.6±4.0	0.53*
Previous prolapse surgery[a]	13 (25)	8 (15)	0.19**
Previous continence surgery[a]	2 (4)	3 (6)	0.68**
Baseline POP-Q[a]:			
Stage 2	37 (71)	31 (57)	0.32**
Stage 3	14 (27)	22 (41)	
Stage 4	1 (2)	1 (2)	
Mean point Aa (cm)	0.5±1.5	0.6±1.6	
Mean point Ba (cm)	0.6±1.9	1.2±2.0	
Mean point C (cm)	−2±3.8	−1.3±3.5	

*p value was calculated using Student's t test; **p value was calculated using the χ^2 test

[a]Values given as n (%)

Table 2 Concomitant surgical procedures and perioperative variables

Variable	Prolift® (n=52)	Perigee® (n=54)	p value
Vaginal hysterectomy + sacrospinous colpopexy + posterior colporrhaphy	8 (15)	6 (11)	0.70*
Sacrospinous colpopexy + posterior colporrhaphy	18 (35)	17 (32)	
Sacrospinous hysteropexy + posterior colporrhaphy	26 (50)	31 (57)	
TVT-O	18 (35)	17 (32)	0.73*
Mean operative time ± SD (min)[a]	71.0±25.4	66.7±24.0	0.46**
Mean blood loss ± SD (ml)	247±142	213±117	0.25**
Median (range) hospital stay (days)	4 (2–7)	4 (2–9)	0.78**
Median (range) catheter (IDC + CISC) use (days)	3 (1–180)	2 (1–420)	0.93**
Median (range) time to ADL (days)	21 (7–90)	21 (7–60)	0.81**

TVT-O Tension-free vaginal tape obturator, *IDC* indwelling catheter, *CISC* clean intermittent self-catheterization, *ADL* activities of daily living

*p value was calculated using the χ^2 test; **p value was calculated using the Wilcoxon rank sum test

Values for concomitant surgical procedures are given as n (%)

[a] For all operative procedures combined

power of 84% for 10% inferiority and 95% for 15% inferiority. As both these products consist of a type one monofilament polypropylene mesh and both utilize the obturator foramen for lateral fixation, this similarity is reasonable. Similar anatomical cure rates were reported by Nguyen et al. [2] (89%) 1 year after Perigee® implantation in a randomized controlled trial comparing Perigee® to anterior colporrhaphy and by Altman et al. [6] (82.3%) for Anterior Prolift®. The slightly lower success rates observed in these studies including ours as compared to two retrospective trials evaluating Prolift® [9] and Perigee® [10] separately may be explained by the more rigorous evaluation undertaken in prospective comparative studies. A single retrospective study [15] comparing Perigee®/Apogee® with Anterior and/or Posterior Prolift® systems was identified at the literature search, demonstrating equivalent recurrence rates (without details on the site of recurrence) despite a significant difference in follow-up durations between the two study groups.

Table 3 POP-Q measurements and APFQ scores at follow-up

Variable	Prolift®	Perigee®	p value*
Point Aa (cm)	−2.1±0.6	−1.9±0.5	0.26
Point Ba (cm)	−2.1±0.6	−1.9±0.5	0.26
Point C (cm)	−7.4±2.0	−7.3±2.1	0.77
Point Bp (cm)	−2.1±0.6	−2.2±0.5	0.69
TVL (cm)	8.8±0.6	8.8±0.4	0.53
Bladder score[a]	1.9±1.3	1.8±1.5	0.80
Bowel score[a]	2.0±1.3	1.9±1.0	0.61
Prolapse score[a]	0.7±1.4	0.7±1.3	0.85
Sexual score[a]	1.1±1.4	1.0±1.5	0.81
Total score[a]	5.6±3.4	5.4±4.5	0.75

Values given as mean ± SD

*p value was calculated using Student's t test

[a] Australian pelvic floor questionnaire

Subjective success rates in both groups at the present study were similarly high (94% Prolift; 96% Perigee), suggesting that a proportion of women, who were classified as anatomical failures, were in fact free of prolapse symptoms. This finding raises a question whether the definition of anatomical failure (stage II or greater prolapse, either symptomatic or not) that was used in our trial and commonly employed by other researchers should be adopted as a standard in all surgical trials or maybe a different definition, which more realistically reflects what patients sense as a failure should be used.

While perioperative and postoperative complications were similarly prevalent in both groups, the rates of mesh erosion, contraction, and de novo dyspareunia (Prolift, 11%; Perigee, 16%) are in accordance with reported case series [16–18] on pelvic floor reconstructions using either mesh kits or self-styled polypropylene grafts. Postoperative dyspareunia may also be attributed to the addition of sacrospinous fixation as previously shown by Maher [19] and by Nieminen [20]. These potential complications should be taken into account when offering a surgical intervention to patients who are sexually active, in particular at younger age groups.

The strength of this study is being a prospective comparison to establish no significant difference between the more rigorously evaluated Perigee® and the widely utilized Anterior Prolift® including objective and subjective outcome measures, validated pelvic floor questionnaires, and patient satisfaction with a reviewer blinded to patient allocation. Potential limitations to our conclusions include the lack of randomization, the limited median follow-up

duration of 11 months, and the fact that a larger sample size may have been able to detect more subtle differences between these two commercial kits for anterior compartment prolapse. However, given the equal distribution between the two procedures for preoperative demographics, prior continence or prolapse surgery, degree of prolapse, and rates of SUI, we are confident that the patients have been equally distributed for possible known confounders between the two interventions. With new prolapse repair kits being introduced in an ever growing pace, clinical data demonstrating equipoise should be made available without delay to patients and practitioners while awaiting more rigorous evaluation under the auspices of a randomized controlled trial.

We conclude that the Anterior Prolift® and the Perigee® systems achieve similar objective and subjective outcomes, patient satisfaction, quality of life, and complications at 11 months. While equipoise between the Anterior Prolift® and Perigee® has been established, more rigorous evaluation of other commercial mesh kits should be undertaken prior to the assumption that all mesh kits are similar and good anatomical outcomes obtained by few of the anterior compartment prolapse repair systems are fully transferable to other kits.

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Conflicts of interest None.

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