

# Retrospective study of transobturator polypropylene mesh kit for the management of pelvic organ prolapse

Ganesh Raj Vaiyapuri<sup>1</sup>, MBBS, MOG, How Chuan Han<sup>2</sup>, MBBS, FRCOG, Lih Charn Lee<sup>2</sup>, MBBS, MRACOG, Arthur Leng Aun Tseng<sup>3</sup>, MBChB, MRCOG, Heng Fok Wong<sup>4</sup>, MBBS, MRCOG

**INTRODUCTION** This retrospective study assessed the surgical outcomes of patients for whom the transobturator polypropylene mesh kit was used for the management of pelvic organ prolapse (Gynecare Prolift®) in a tertiary urogynaecological centre in Singapore from January 1, 2006 to December 31, 2007.

**METHODS** 169 patients (2006 n = 95; 2007 n = 74) with total (n = 76), anterior (n = 82) and posterior (n = 11) Prolifts were followed up for two years post-surgery.

**RESULTS** Intraoperatively, the incidence of haematoma, blood loss > 1,000 mL and blood transfusion was lower in 2007 than in 2006, although the difference was not statistically significant. One (1.4%) patient had rectal perforation in 2007. The mesh erosion rates were similar for all Prolift types (total 17.2%; posterior 14.5%; anterior 18.2%). Two patients, who had total Prolift in 2006, required mesh excision under anaesthesia for mesh extrusion. 138 (81.7%) patients were available for review at two years – nine (6.5%) patients had recurrent cystourethrocoeles and two (1.4%) had recurrent vault prolapse. Of the nine patients who had total Prolift with uterine conservation, two (1.4%) had recurrent uterine descent. The subjective cure rates two years after Prolift surgery were 98.7% for patients from 2006 and 100% for patients from 2007. The objective cure rates were 89.6% for patients from 2006 and 91.8% for patients from 2007.

**CONCLUSION** Prolift mesh surgery appears to have a very high success rate for pelvic reconstructive surgery. The learning curve of the surgeon may, however, be a factor determining surgical outcome in these patients.

*Keywords: pelvic organ prolapse, prolift mesh, surgery, treatment outcome*  
*Singapore Med J 2012; 53(10): 664–670*

## INTRODUCTION

The lifetime risk of pelvic organ prolapse (POP) in parous women over 50 years of age is approximately 30%–50%.<sup>(1)</sup> The risk of reoperation after failed corrective surgery is up to 29%.<sup>(2)</sup> Traditional surgical repair of POP (particularly cystocele repair) is associated with high failure rates and may even result in a shortening or constricting of the vagina.<sup>(3)</sup> Although paravaginal corrective surgeries may yield better anatomical support, they do not appear to be superior to the traditional non-mesh incorporated repairs.<sup>(4)</sup> The use of synthetic materials vaginally enhances long-term functional results and increases the durability of repair.

The Gynecare Prolift kit (Ethicon, Somerville, NJ, USA) is a type 1 synthetic macroporous monofilament polypropylene mesh utilising a trocar-based delivery system. It is devised to serve as a scaffold or bridge that allows the native tissue to grow, which further enhances the durability of pelvic floor repair, thus conferring long-term support. Huebner et al<sup>(5)</sup> suggested that the use of such mesh-augmented repairs is questionable due to the limited data that is available. Currently, it appears to be the best technique, as it is able to combine the superior success rate of abdominal sacrocolpopexy with the low morbidity of a vaginal approach.<sup>(6)</sup> The primary aim of this study was to evaluate and compare the two-year outcome of Prolift in patients who underwent surgery in 2006 and 2007 at a tertiary urogynaecological centre in Singapore.

The secondary aim was to establish if the learning curve of pelvic reconstructive surgeons had an impact on the outcomes in these patients.

## METHODS

This was a non-funded, retrospective review of data collected from the medical records of 169 patients who underwent mesh-augmented surgical correction for stage 4 or recurrent POP using the Gynecare Prolift system at our urogynaecological centre from January 1, 2006 to December 31, 2007. The study was approved by the Central Institutional Review Board (CIRB) Ethics Committee. No consent was obtained from the patients, as it was a retrospective review and a waiver of consent was approved by the CIRB. No financial assistance was received from any company for the execution of this study.

Preoperatively, all patients underwent a comprehensive and detailed urogynaecological and medical review. Clinical examination was carried out, and freshly voided urine was taken for microscopy and culture to exclude urinary tract infection (UTI). POP was graded using the modified International Continence Society (ICS) POP ordinal staging system (Table I).<sup>(7)</sup> Urodynamic studies (UDS), including uroflowmetry, residual urine volume measurement, filling and voiding cystometry, and urethral pressure profilometry were performed according to the standards recommended by the ICS and to detect any occult

<sup>1</sup>Urogynaecology Unit, Department of Obstetrics and Gynaecology, Hospital Tengku Ampuan Afzan, Kuantan, Malaysia, <sup>2</sup>Urogynaecology Department, KK Women's and Children's Hospital, Singapore, <sup>3</sup>Gleneagles Medical Centre, Singapore, <sup>4</sup>Thomson Women's Clinic, Singapore

**Correspondence:** Dr Ganesh Raj Vaiyapuri, Urogynaecology Subspecialty Trainee, Urogynaecology Unit, Department of Obstetrics and Gynaecology, Hospital Tengku Ampuan Afzan, 25000 Kuantan, Pahang, Malaysia. rajfeelsgood@yahoo.com

stress urinary incontinence (SUI). Postoperatively, patients were reviewed at one week, one month, six months, 12 months and annually thereafter. At each visit, a urogynaecological assessment was performed. UDS was repeated at six months if the patient had a concomitant continence surgery. During each follow-up, a detailed history of the patient's lower urinary tract symptoms and sexual function were elicited to exclude any *de novo* urge incontinence or urgency, as well as to rule out any sexual dysfunction as a result of the surgery.

The Prolift mesh is a pre-cut, non-absorbable, macroporous, monofilament soft synthetic mesh that has three distinct components – anterior, posterior and total Prolift mesh systems. The technique of insertion was as described by Fatton et al.<sup>(6)</sup> The procedure was carried out under either general or regional anaesthesia, at the discretion of the anaesthetist and based on the suitability of the patient. All subjects were placed in a dorsal lithotomy position with thighs flexed at about 90° to 110°. Preoperative antibiotic prophylaxis was administered parenterally, with intravenous cefazoline and metronidazole for coverage of both Gram-positive and Gram-negative microbes.

The synthetic mesh was inserted tension-free, avoiding any possible crumpling or folding, and vicryl 'O' sutures were used for temporary fixation of the mesh anteriorly and posteriorly. The incised vaginal wall epithelium was closed with continuous 2/0 vicryl sutures. After surgery, an indwelling Foley's catheter was inserted into the bladder and a vaginal pack soaked with povidone inserted into the vagina for tamponade to reduce haematoma formation. Both the indwelling catheter (IDC) and the vaginal pack were removed after 48 hours by the attending team of doctors. Concomitant surgical procedures, such as vaginal hysterectomy, pelvic floor repair, sacrospinous ligament fixation and continence procedures (such as tension-free vaginal tape [TVT], tension-free vaginal tape-obturator [TVT-O] or tension-free vaginal tape-secure [TVT-S]) were performed when necessary. All the patients in the study were operated on by the same surgeon.

The subjective and objective cure rates were recorded. The patient was considered cured if she did not feel a lump in her vagina postoperatively. Objective cure was determined as pelvic organ descent/prolapse not greater than stage 1 during postoperative examination. Recurrent prolapse was defined as any prolapse or herniation of the pelvic organ of stage 2 and beyond, irrespective of whether the patient was symptomatic or not. Statistical analysis was performed using the Statistical Package for the Social Sciences for Windows version 14 (SPSS Inc, Chicago, IL, USA) and the chi-square test. The Student's *t*-test and Fisher's exact test were used for categorical variables.

Of the 169 patients recruited in the study (2006 *n* = 95; 2007 *n* = 74), 76 patients had total, 82 had anterior and 11 had posterior Prolifts. They were followed up for two years after surgery. Patients who defaulted on follow-up (defaulters) were contacted via telephone, and at least three attempts were made before they were categorised as lost to follow-up. For deceased patients, deaths were verified with the National Death Registry

**Table I. The modified International Continence Society pelvic organ prolapse ordinal staging system.**

Stage	Feature
0	No prolapse
1	When the leading part of the prolapse has descended to not more than 1 cm above the hymeneal ring
2	Descent within 1 cm above or below the hymeneal ring
3	Descent more than 1 cm beyond the hymeneal ring
4	When the prolapse lies completely beyond the hymeneal ring

**Table II. Patients who attended follow-up two years after surgery.**

Detail	No. (%)		
	2006	2007	Total
<b>Non-defaulters</b>	77 (81.1)	61 (82.4)	138 (81.7)
Total Prolift	26	32	
Anterior Prolift	45	24	
Posterior Prolift	6	5	
<b>Defaulters</b>	18 (18.9)	13 (17.6)	31* (18.3)
Total Prolift	9	9	
Anterior Prolift	9	4	
Posterior Prolift	0	0	

\*Two patients died.

and the cause of death established. Table II shows the number of defaulters by year and type of Prolift surgery. 138 (81.7%) patients were available for the two-year follow-up, with 31 (18.3%) defaulters in all. Two patients who underwent the operation in 2006 (total Prolift *n* = 1; anterior Prolift *n* = 1) died of other medical reasons. The first patient succumbed to cardiac failure eight months after surgery, while the second succumbed to advanced colorectal malignancy detected 18 months post operation.

## RESULTS

Table III describes the baseline characteristics, presenting symptoms and history of previous surgery of the patients who underwent Prolift-augmented pelvic reconstructive surgery (*n* = 169; age range 42–89 years). The number of patients available for the two-year follow-up from the 2006 and 2007 groups were comparable, as were the mean and median follow-up periods for the two years (2006: mean 698.49 ± 330.73 days, median 730.00 days; 2007: mean 704.07 ± 271.41 days, median 732.50 days). The combined mean and median follow-up periods for patients in 2006 and 2007 were 700.94 ± 305.31 days and 730.00 days, respectively.

40 (23.7%) patients were sexually active, and four (10.0%) patients experienced dyspareunia. Only three (2.0%) postmenopausal patients were on hormone replacement therapy. The predominant clinical presentation was a lump or bulge at the introitus (97.6%). 40 (23.7%) patients had SUI and 53 (31.4%) patients had voiding difficulties. The demographic characteristics of patients from 2006 and 2007 were otherwise similar.

Preoperative UDS in 160 patients showed the presence of urodynamic stress incontinence (12.5%), detrusor overactivity

Table III. Baseline characteristics of patients.

Characteristic	No. (%)			p-value
	2006 (n = 95)	2007 (n = 74)	Total (n = 169)	
Age* (yr)	64.4 ± 9.0	63.8 ± 9.9	64.3 ± 9.7	0.675
Parity*	3.5 ± 2.4	4.0 ± 2.3	3.7 ± 2.3	0.361
BMI* (kg/m <sup>2</sup> )	25.1 ± 3.7	25.7 ± 3.7	25.3 ± 3.7	0.340
Sexually active patients	22 (23.2)	18 (24.3)	40 (23.7)	0.501
Dyspareunia <sup>†</sup>	1 (4.5)	3 (16.7)	4 (10.0)	0.436
Menopausal patients	84 (88.4)	66 (89.2)	150 (88.8)	0.538
Hormone replacement therapy	3 (3.2)	0	3 (2.0)	0.175
<b>Presenting symptom</b>				
Frequency	17 (17.9)	22 (29.7)	39 (23.1)	0.052
Nocturia	42 (44.7)	29 (39.2)	71 (42.0)	0.289
Stress urinary incontinence	27 (28.4)	13 (17.6)	40 (23.7)	0.071
Urgency	38 (40.0)	32 (43.2)	70 (41.4)	0.394
Urge incontinence	22 (23.2)	20 (27.0)	42 (24.9)	0.344
Voiding difficulty	24 (25.3)	29 (39.2)	53 (31.4)	0.039
Lump	92 (96.8)	73 (98.6)	165 (97.6)	0.409
Faecal incontinence	3 (3.2)	1 (1.4)	4 (2.4)	0.415
<b>Prior history</b>				
Urogynaecological surgery	24 (25.3)	15 (20.3)	39 (23.1)	0.282
Abdominal hysterectomy	35 (36.8)	16 (21.6)	51 (30.2)	0.345
Burch colposuspension	8 (8.4)	5 (7.6)	13 (7.7)	0.298
Transvaginal incontinence surgery	6 (6.3)	6 (8.1)	12 (7.1)	0.453

\*Data is presented as mean ± standard deviation. <sup>†</sup>In 40 sexually active patients. BMI: body mass index

Table IV. Indications for Prolift surgery.

Indication	Type of Prolift		
	Total (n = 76)	Anterior (n = 82)	Posterior (n = 11)
Age* (yr)	47 (61.8)	-	-
Parity*	20 (26.4)	-	-
BMI* (kg/m <sup>2</sup> )	9 (11.8)	-	-
Sexually active patients	-	68 (82.9)	-
Dyspareunia <sup>†</sup>	-	14 (17.1)	-
Menopausal patients	-	-	4 (36.4)
HRT	-	-	0
Prior history	-	-	7 (63.6)

Data is presented as number of patients (%). BMI: body mass index; HRT: hormone replacement therapy

(6.9%) and mixed incontinence (0.6%). Preoperative ultrasonography of the kidneys was done for 96 (56.8%) patients, among whom 25 (26.0%) patients had hydronephrosis that resolved postoperatively. Although four (1.6%) patients had a history of faecal incontinence at their first visit, assessments did not reveal any obvious anal sphincter defect. All four patients were referred to a colorectal unit for further assessment, but none warranted concomitant faecal continence surgery at the time of Prolift surgery. Table IV provides the indications observed among patients undergoing total, anterior and posterior Prolift surgeries.

A concomitant continence procedure of mid-urethral sling was performed in patients with coexisting SUI by making a separate incision. TVT-O was done for most patients (n = 33, 19.5%) (Table V). TVT and TVT-S were done in two (1.2%) patients each. Nine patients had Prolift mesh surgery with uterine conservation

(2006 n = 7; 2007 n = 2). 103 (60.9%) patients had a concomitant vaginal hysterectomy.

The estimated blood loss (EBL), duration of surgery and length of hospital stay in our patients (Table V) were comparable to those in the literature.<sup>(9)</sup> Higher EBL (p = 0.004) and longer duration of surgery (p = 0.001) were seen among patients who had total Prolifts compared to those having anterior or posterior Prolift surgeries. A majority of patients (n = 92, 54.4%) were hospitalised for two days postoperatively. One patient who had anterior Prolift was hospitalised for 39 days. This patient required blood transfusion and exploration under anaesthesia four hours after the procedure to secure a bleeding ovarian pedicle, and subsequently developed a pelvic abscess that required drainage under ultrasonographic guidance. The mean duration of IDC was 3.0 ± 2.9 (range 1–19) days. The IDC was taken off two days after the Prolift surgery for 124 (73.4%) patients. Subanalysis revealed that the type of Prolift surgery had no significant impact on the duration of IDC or the length of hospital stay.

Serious perioperative complications – vault bleeding that required exploratory laparotomy (n = 2), pelvic haematoma with disseminated intravascular coagulation (n = 1), vaginal wall haematoma (n = 1), bleeding from a gluteal puncture wound (n = 1) and a slipped ovarian pedicle ligature (n = 1) – were seen in six (3.6%) patients who underwent total Prolift surgeries (p = 0.022) (Table VI). All such complications were identified early and treated without any long-term effects. Five of these patients with complications were operated on in 2006 (Table VII). Only one patient who required blood transfusion as a result of haemorrhage had total Prolift surgery in 2007. Significant blood loss (> 1,000 mL) requiring blood transfusion was significantly

Table V. Details of surgery.

Detail	Type of Prolift			Total (n = 169)	p-value
	Total (n = 76)	Anterior (n = 82)	Posterior (n = 11)		
<b>Anaesthesia</b>					
General	11 (14.5)	13 (15.9)	1 (9.1)	25 (14.8)	0.943
Regional	65 (85.5)	69 (84.1)	10 (90.9)	144 (85.2)	0.943
<b>Concomitant surgery</b>					
Vaginal hysterectomy	45 (59.2)	57 (69.5)	1 (9.1)	103 (60.9)	0.001*
Posterior repair	62 (81.6)	69 (84.1)	10 (90.9)	141 (83.4)	0.802
Sacrospinous ligament fixation	0	46 (56.1)	0	46 (27.2)	0.001*
Tension-free vaginal tape	0	2 (2.4)	0	2 (1.2)	0.561
Tension-free vaginal tape-obturator	13 (17.1)	19 (23.2)	2 (9.1)	33 (19.5)	0.497
Tension-free vaginal tape-secur	1 (1.3)	1 (1.2)	0	2 (1.2)	1.000
<b>Estimated blood loss (mL)</b>	174.6 ± 285.5	84.0 ± 59.2	23.2 ± 28.7	120.2 ± 200.5	0.004*
<b>Duration of surgery (min)</b>	85.4 ± 25.7	70.6 ± 28.0	38.4 ± 19.6	77.8 ± 28.3	0.001*
<b>Duration of indwelling catheter (days)</b>	3.0 ± 2.4	76.3 ± 26.8	2.0 ± 1.1	3.0 ± 2.9	0.483
<b>Length of hospital stay (days)</b>	3.6 ± 4.8	3.1 ± 1.2	2.6 ± 1.2	3.1 ± 3.3	0.235

Data is presented as number of patients (%) or mean ± standard deviation. \*p < 0.05 was statistically significant.

Table VI. Perioperative complications by type of Prolift.

Complication	Type of Prolift			Total (n = 169)	p-value
	Total (n = 76)	Anterior (n = 82)	Posterior (n = 11)		
<b>Intraoperative complication</b>					
Haematoma	6 (7.9)	0	0	6 (3.6)	0.022*
Bleeding > 1,000 mL	5 (6.6)	0	0	5 (3.0)	0.043*
Blood transfusion	7 (9.2)	0	0	7 (4.1)	0.011*
Anal perforation	1 (1.3)	0	0	1 (0.6)	0.540
<b>Postoperative complication</b>					
Fever	29 (38.2)	22 (25.6)	7 (63.6)	57 (33.7)	0.024*
Urinary tract infection	2 (2.7)	1 (1.2)	0	3 (1.8)	0.716
Indwelling catheter ≥ 7 days	6 (7.9)	6 (7.3)	0	12 (7.1)	0.632
Thigh pain	16 (21.1)	24 (29.3)	0	40 (23.7)	0.077
Buttock pain	12 (15.8)	11 (13.4)	3 (27.3)	26 (15.4)	0.485
Voiding difficulty	21 (27.6)	16 (19.5)	1 (9.1)	38 (22.5)	0.259

Data is presented as number of patients (%). \*p < 0.05 was statistically significant.

Table VII. Perioperative complications by year of surgery.

Complication	No. (%)			p-value
	2006 (n = 95)	2007 (n = 74)	Total (n = 169)	
<b>Intraoperative complication</b>				
Haematoma	5 (5.3)	1 (1.4)	6 (3.6)	0.230
Bleeding > 1,000 mL	4 (4.2)	1 (1.4)	5 (3.0)	0.391
Blood transfusion	5 (5.3)	2 (2.7)	7 (4.1)	0.470
Anal perforation	0 (0)	1 (1.4)	1 (0.6)	0.258
<b>Postoperative complication</b>				
Fever	33 (34.7)	24 (32.4)	57 (33.7)	0.755
Urinary tract infection	1 (1.1)	2 (2.7)	3 (1.8)	0.435
Indwelling catheter ≥ 7 days	7 (7.4)	5 (6.8)	12 (7.1)	0.879
Thigh pain	28 (29.5)	12 (16.2)	40 (23.7)	0.045*
Buttock pain	20 (21.1)	6 (8.1)	26 (15.4)	0.031*
Voiding difficulty	20 (21.1)	18 (24.3)	38 (22.5)	0.616

\*p < 0.05 was statistically significant.

higher in patients following total Prolift surgery than the other Prolift procedures.

Rectal perforation (size ~ 1 cm) was seen on the right side in one patient in 2007 during total Prolift surgery, which was identified intraoperatively and repaired with a two-layered closure using absorbable sutures. Postoperatively, computed tomography (CT)

imaging of the patient's pelvis revealed minimal fluid collection at the vault area, which resolved without any further intervention. The patient developed postoperative UTI, which was treated with the appropriate antibiotic therapy. She was discharged well on postoperative Day 11. 57 (33.7%) patients developed fever following Prolift procedures in our study. The mean duration of

**Table VIII. Late complications by type of Prolift two years after surgery.**

Complication	Type of Prolift			Total (n = 169)	p-value
	Total (n = 76)	Anterior (n = 82)	Posterior (n = 11)		
<i>De novo</i> stress urinary incontinence	5 (8.6)	8 (11.6)	1 (9.1)	14 (10.1)	0.909
<i>De novo</i> urge urinary incontinence	3 (5.2)	7 (10.1)	1 (9.1)	11 (8.0)	0.483
Wound dehiscence	4 (6.9)	3 (4.3)	1 (9.1)	8 (5.8)	0.621
Mesh erosion	10 (17.2)	10 (14.5)	2 (18.2)	22 (15.9)	0.827
Dyspareunia	0	0	0	0	-
Pelvic pain	0	0	0	0	-
Reoperation*	2 (3.4)	0	0	2 (1.4)	0.329

Data is presented as number of patients (%). \*Both patients who underwent total Prolift in 2006 had mesh erosion and vaginal pain, requiring mesh excision. One patient needed closure of the vaginal skin.

**Table IX. Two-year outcome by type of Prolift.**

Outcome	Type of Prolift			Total (n = 169)	p-value
	Total (n = 76)	Anterior (n = 82)	Posterior (n = 11)		
<b>Cure rate</b>					
Subjective cure	58 (100.0)	69 (100.0)	10 (90.9)	137 (99.3)	0.080
Objective cure	48 (82.8)	66 (95.7)	11 (100.0)	125 (90.6)	0.038 <sup>†</sup>
<b>Recurrence rate</b>	10 (17.2)	3 (4.3)	0	13 (9.4)	0.038 <sup>†</sup>
Recurrent cystourethrocoele	6 (10.3)	3 (4.3)	NA	9 (6.5)	0.299
Recurrent vault prolapse	2 (3.4)	NA	0	2 (1.4)	1.000
Recurrent uterine descent*	2 (3.4)	NA	NA	2 (1.4)	0.207

Data is presented as number of patients (%). \*Both patients had prolapsed uterus following uterine conservation surgery and subsequently underwent vaginal hysterectomy. <sup>†</sup>p < 0.05 was statistically significant. NA: not applicable

fever was  $1.4 \pm 0.7$  (range 1–5) days. 39 (23.1%) patients had fever that lasted just one day. 40 (23.7%) patients developed transient thigh pain (mean duration  $3.5 \pm 2.3$  days), while 26 (15.4%) patients had buttock pain (mean duration  $4.4 \pm 4.5$  days). One (0.6%) patient had buttock pain that lasted 23 days, which resolved spontaneously with adequate analgesia.

Only 138 (82%) patients of the 169 who underwent Prolift surgeries in 2006 and 2007 continued with follow-up two years after surgery (Table VIII; total Prolift n = 58; anterior Prolift n = 69; posterior Prolift n = 11). Patients who had posterior Prolift surgeries did not default on follow-up two years after the procedure (total Prolift n = 18, 23.7%; anterior Prolift n = 13, 15.9%; posterior Prolift n = 0, 0%).

14 (10.1%) patients developed *de novo* SUI, and two (14.2%) patients subsequently underwent TVT-O during the follow-up period. Although 40 (23.7%) patients were sexually active prior to surgery, only 15 (10.6%) still engaged in sexual activity at the two-year follow-up. None of the patients complained of *de novo* dyspareunia postoperatively. Wound dehiscence was identified in eight (5.8%) patients and mesh erosion in 22 (15.9%) patients. The earliest appearance of wound dehiscence was at three weeks after surgery, and most healed spontaneously in two months.

In our study, mesh erosions occurred mainly in patients after total and anterior Prolift surgeries, with the complication being reported in only two patients from the posterior Prolift cohort. The mean duration of detection of mesh erosion was  $7.4 \pm 1.1$  months. All mesh erosions were treated empirically with local oestrogen therapy (premarin cream or vagifem pessaries). Two (1.4%) patients from the 2006 cohort, who progressed to mesh

extrusion, required mesh excision and vaginal skin overlay. However, secondary mesh infections or fistula formation was not noted in any patient.

Almost all (99.3%) patients who underwent Prolift surgeries were satisfied with the treatment received (Table IX). Recurrent cystourethrocoeles were more common among patients who underwent total Prolift surgery (total Prolift n = 6, 10.3%; anterior Prolift n = 3, 4.3%). In total, recurrence was seen in ten (17.2%) patients who had total Prolift surgery – recurrent cystourethrocoele (n = 6, 10.3%), recurrent vault prolapse (n = 2, 3.4%) and recurrent uterine descent that required subsequent vaginal hysterectomy in patients who had uterine conservation surgery (n = 2, 3.4%). The subjective and objective cure rates for posterior Prolift patients were 90.9% and 100%, respectively.

A reduction, although not statistically significant, was seen in the incidence of *de novo* SUI (4.9% vs. 14.3%) and *de novo* urge urinary incontinence (3.3% vs. 11.7%) at two years in the 2007 cohort when compared to patients in 2006 (Table X). Postoperative wound dehiscence was not seen in any patient in 2007 as compared to eight patients in 2006 (0% vs. 10.4%; p = 0.009). Mesh erosion rate was also significantly lower in 2007 than in 2006 (6.6% vs. 23.4%; p = 0.009). None of the patients complained of dyspareunia or pelvic pain at the two-year follow-up.

The number of patients from 2006 and 2007 having recurrent cystourethrocoeles (2006 n = 4; 2007 n = 5) and recurrent vault prolapse (2006 n = 2; 2007 n = 0) at the two-year follow-up were not significantly different. Similarly, only two (1.4%) patients out of nine who underwent total Prolift and uterine conservation



Table X. Late complications by year of surgery.

Characteristic	No. (%)			p-value
	2006 (n = 95)	2007 (n = 74)	Total (n = 169)	
<b>Patients on follow-up</b>	77 (81.1)	61 (82.4)	138 (81.7)	0.844
<b>Late complications</b>				
<i>De novo</i> stress urinary incontinence	11 (14.3)	3 (4.9)	14 (10.1)	0.091
<i>De novo</i> urge urinary incontinence	9 (11.7)	2 (3.3)	11 (8.0)	0.111
Wound dehiscence	8 (10.4)	0	8 (5.8)	0.009 <sup>†</sup>
Mesh erosion	18 (23.4)	4 (6.6)	22 (15.9)	0.009 <sup>†</sup>
Dyspareunia	0	0	0	-
Pelvic pain	0	0	0	-
Reoperation*	2 (2.6)	0	2 (1.4)	0.503
<b>Cure rate</b>				
Subjective cure	76 (98.7)	61 (100.0)	137 (99.3)	1.000
Objective cure	69 (89.6)	56 (91.8)	125 (90.6)	0.774
<b>Recurrence rate</b>	8 (10.4)	5 (8.2)	13 (9.4)	0.664
Recurrent cystourethrocoele	4 (5.2)	5 (8.2)	9 (6.5)	0.763
Recurrent vault prolapse	2 (2.6)	0	2 (1.4)	0.775
Recurrent uterine descent	2 (2.6)	0	2 (1.4)	0.208

\*Both patients who underwent total Prolift in 2006 had mesh erosion and vaginal pain, requiring mesh excision. One patient needed closure of the vaginal skin.

<sup>†</sup> p < 0.05 was statistically significant.

surgeries had recurrent uterine descent. The subjective and objective cure rates two years after Prolift surgery were slightly higher for the 2007 cohort (2006 subjective cure rate 98.7%, objective cure rate 89.6%; 2007 subjective cure rate 100%, objective cure rate 91.8%).

## DISCUSSION

The use of synthetic mesh in transvaginal pelvic surgeries was pioneered in 1996 by Julian, who demonstrated a significant reduction in the recurrence rate of prolapse when a polypropylene mesh was used to increase the durability of pelvic tissue support.<sup>(10)</sup> Gynecare Prolift is a transvaginal prolapse repair mesh system that combines the superior success rate of a transabdominal approach with the lower complication rates of a transvaginal approach. Our retrospective study, which looked at the two-year outcome of patients who underwent Gynecare Prolift surgeries in a tertiary urogynaecological centre in 2006–2007, obtained high cure rates at two years, indicating that the Gynecare Prolift system is highly effective in achieving good anatomical support for advanced POP. A low threshold for suspecting visceral injury at the time of surgery, in addition to prompt and timely interventions, can prove to be lifesaving in such surgeries. In 2007, Altman and Falconer reported the incidence of serious intraoperative complications to be 4.4% (mostly visceral injuries) in a series of 248 patients with the Prolift system.<sup>(11)</sup> Similarly, de Tayrac et al, who used an alternative Ugytex transvaginal mesh system for 230 patients, reported the rate of serious intraoperative complications as 3.6%.<sup>(12)</sup> The incidence of serious intraoperative complications in our study was 5.1% (haematoma n = 6; rectal perforation n = 1).

Among the three Prolift systems, total Prolift surgeries were associated with higher and statistically significant intraoperative complications. Total Prolift was also associated with longer operation times, greater blood loss and more complications, in part due to the increased dissection required. For patients who

required total Prolift due to recurrent prolapse after previous failed surgeries, the operation was more complex, as tissue planes were more difficult to identify due to fibrosis and scarring from chronic prolapse or previous surgery. Furthermore, the blind insertion of the six extension arms of the total Prolift system, when compared to the four arms of the anterior Prolift or the two arms of the posterior Prolift systems, might have resulted in higher morbidity rates.

Properties attributed to an ideal mesh include those with foreign material that exerts minimal foreign body reaction, poses minimal risk of infection, exhibits minimal risk of rejection and has minimal risk of erosion. Deffieux et al reported the mesh erosion rate to be 20% for patients needing transvaginal repair of cystocele using Gynemesh.<sup>(13)</sup> At the two-year follow-up, the mesh erosion rate in our study was similar for total and anterior Prolift surgeries and lower for posterior Prolift surgery. The site of mesh erosion was predominantly the anterior vaginal wall (65%) at the previous vertical midline incision. Erosions also occurred at the vault (25%) and posterior vaginal wall (10%). Management of vaginal erosion was relatively straightforward. For asymptomatic patients, conservative treatment was always attempted initially, as the risk of sepsis is considered minimal with a macroporous mesh.<sup>(14)</sup> Conservative management of erosion included vaginal oestrogen therapy and antibiotics. For symptomatic patients, the excision of the extruded mesh is necessary.<sup>(15,16)</sup>

In our study, only two patients who were operated on in 2006 required partial excision of the total Prolift mesh. None of the patients who underwent anterior and posterior surgeries needed such an excision. Studies have suggested that the surgeon's experience, reduced length of the vaginal incision, avoidance of an inverted T-shaped incision during hysterectomy, as well as the avoidance of electrical cauterisation and careful dissection after infiltration, were key factors that enhanced vaginal wall healing and integrity, with a consequently reduced rate of mesh erosion.<sup>(17)</sup> We too found that the rate of mesh erosion in patients who underwent

the operation in 2007 declined remarkably with the increasing experience of the surgeon involved.

Milani et al, who reported an increased incidence of dyspareunia after anterior repair with a prolene mesh (20%) and posterior repair reinforced by mesh (63%),<sup>(18)</sup> recommended abandoning mesh-augmented surgical methods. Other uncontrolled trials have reported dyspareunia rates ranging from 10% to 36% after using polypropylene mesh.<sup>(19-21)</sup> Hispareunia can also occur when the exposed mesh in the vagina leads to pain during intercourse for the male partner.<sup>(22)</sup> However, a reduction in dyspareunia rates after mesh surgery has also been described by some studies.<sup>(23,24)</sup>

On comparing the surgical outcomes at two years for the 2006 and 2007 cohorts, we concluded that the surgeon's learning curve was a factor for favourable perioperative outcome, as success rates were higher in 2007 when compared to 2006. In 2007, the incidence of thigh and buttock pains was statistically lower than in 2006. The incidences of haematomas, blood loss > 1,000 mL and blood transfusion requirements were also lower, although the difference was not statistically significant.

In conclusion, Gynecare Prolift is a safe and effective treatment for advanced or recurrent POP, with high subjective and objective cure rates two years after surgery. Total Prolift mesh recipients had more perioperative complications in comparison to patients receiving the other two Prolift meshes. The cure rate in patients who desired uterine conservation was lower. Larger randomised prospective trials with longer follow-up periods are needed to establish the efficacy and safety of the Prolift mesh system for the treatment of advanced and recurrent POPs.

## REFERENCES

- Subak LL, Waetjen LE, van den Eeden S, et al. Cost of pelvic organ pelvic surgery in the United States. *Obstet Gynecol* 2001; 98:646-51.
- 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.
- Hiltunen R, Nieminen K, Takala T, et al. Low-weight polypropylene mesh for anterior vaginal wall prolapse: a randomized controlled trial. *Obstet Gynecol* 2007; 110:455-62.
- Maher C, Baessler K. Surgical management of anterior vaginal wall prolapse: an evidencebased literature review. *Int Urogynecol J Pelvic Floor Dysfunct* 2006; 17:195-201.
- Huebner M, Hsu Y, Fenner DE. The use of graft materials in vaginal pelvic floor surgery. *Int J Gynaecol Obstet* 2006; 92:279-88.
- Benson JT, Lucente V, McClellan E. Vaginal versus abdominal reconstructive surgery for the treatment of pelvic support defects: a prospective randomized study with long-term outcome evaluation. *Am J Obstet Gynecol* 1996; 175:1418-21.
- Bump RC, Mattiasson A, Bo K, et al. The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. *Am J Obstet Gynecol* 1996; 175:10-7.
- Fatton B, Amblard J, Debodinance P, Cosson M, Jacquetin B. Transvaginal repair of genital prolapse: preliminary results of a new tension-free vaginal mesh (Prolift technique) – a case series multicentric study. *Int Urogynecol J Pelvic Floor Dysfunct* 2007; 18:743-52.
- Iglesia CB, Fenner DE, Brubaker L. The use of mesh in gynecologic surgery. *Int Urogynecol J Pelvic Floor Dysfunct* 1997; 8:105-15.
- Julian TM. The efficacy of Marlex mesh in the repair of severe, recurrent vaginal prolapse of the anterior midvaginal wall. *Am J Obstet Gynecol* 1996; 175:1472-5.
- Altman D, Falconer C. Perioperative morbidity using transvaginal mesh in pelvic organ prolapse repair. *Obstet Gynecol* 2007; 109:303-8.
- de Tayrac R, Devoldere G, Renaudie J, et al. Prolapse repair by vaginal route using a new protected low-weight polypropylene mesh: 1-year functional and anatomical outcome in a prospective multicentre study. *Int Urogynecol J Pelvic Floor Dysfunct* 2007; 18:251-6.
- Deffieux X, de Tayrac R, Huel C, et al. Vaginal mesh erosion after transvaginal repair of cystocele using Gynemesh or Gynemesh-Soft in 138 women: a comparative study. *Int Urogynecol J Pelvic Floor Dysfunct* 2007; 18:73-9.
- Birch C, Fynes MM. The role of synthetic and biological prostheses in reconstructive pelvic floor surgery. *Curr Opin Obstet Gynecol* 2002; 14:527-35.
- Achtari C, Hiscock R, O'Reilly BA, Schierlitz L, Dwyer PL. Risk factors for mesh erosion after transvaginal surgery using polypropylene (Atrium) or composite polypropylene / polyglactin 910 (Vypro II) mesh. *Int Urogynecol J Pelvic Floor Dysfunct* 2005; 16:389-94.
- Kobashi KC, Govier FE. Management of vaginal erosion of polypropylene mesh slings. *J Urol* 2003; 169:2242-3.
- Webber AM, Walters MD. Anterior vaginal prolapse: review of anatomy and techniques of repair. *Obstet Gynecol* 1997; 89:311-8.
- Milani R, Salvatore S, Soligo M, et al. Functional and anatomical outcome of anterior and posterior vaginal prolapse repair with prolene mesh. *BJOG* 2005; 112:107-11.
- Amrute KV, Eisenberg ER, Rastinehad AR, Kushner L, Badlani GH. Analysis of outcomes of single polypropylene mesh in total pelvic floor reconstruction. *Neurourol Urodyn* 2007; 26:53-8.
- de Tayrac R, Deffieux X, Gervaise A, Chauveaud-Lambling A, Fernandez H. Long-term anatomical and functional assessment of trans-vaginal cystocele repair using a tension-free polypropylene mesh. *Int Urogynecol J Pelvic Floor Dysfunct* 2006; 17:483-8.
- Ansquer Y, Marcollet A, Alves K, et al. Cystocele repair by a synthetic vaginal mesh secured anteriorly through the obturator foramen. *Eur J Obstet Gynecol Reprod Biol* 2004; 115:90-4.
- Brubaker L. Editorial. Partner dyspareunia (hispareunia). *Int Urogynecol J* 2006; 17:311.
- Gauruder-Burmester A, Koutouzidou P, Rohne J, Gronewold M, Tunn R. Follow-up after polypropylene mesh repair of anterior and posterior compartments in patients with recurrent prolapse. *Int Urogynecol J Pelvic Floor Dysfunct* 2007; 18:1059-64.
- Dwyer PL, O'Reilly BA. Transvaginal repair of anterior and posterior compartment prolapse with Atrium polypropylene mesh. *BJOG* 2004; 111:831-6.