Int Urogynecol J (2011) 22:197–203
DOI 10.1007/s00192-010-1259-1

ORIGINAL ARTICLE

Outcome of transvaginal pelvic reconstructive surgery with Prolift after a median of 2 years' follow-up

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Received: 9 May 2010 / Accepted: 20 August 2010 / Published online: 7 September 2010

Abstract
Introduction and hypothesis This study seeks to analyze the medium- to long-term outcome of transvaginal pelvic reconstructive surgery using the Prolift™ system for pelvic organ prolapse.
Methods Sixty-five patients who underwent pelvic floor reconstruction using Prolift™ were followed for 1 to 3 years postoperatively. Assessment included pre- and postoperative Pelvic Organ Prolapse Quantification (POP-Q) stage, Urogenital Distress Inventory (UDI-6), and Incontinence Impact Questionnaire (IIQ-7) scores.
Results The overall anatomic success rate was 97% after a median of 24.5 months and 94% for the 34 women followed for more than 2 years. POP-Q stage, UDI-6, and IIQ-7 scores all improved significantly after surgery. Complications included one bladder perforation (1.5%) and one bowel perforation (1.5%), prolonged catheterization in four patients (6%), and mesh erosion in one (2%). Eight received blood transfusion (12%).
Conclusions Prolift™ surgery yielded a good anatomical outcome and satisfactory symptom improvement that appeared to be durable after 2 years.

Keywords Mesh · Pelvic organ prolapse · Prolift · Transvaginal mesh · Vaginal hysterectomy

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Introduction

As life expectancy increases, disorders associated with aging are also becoming more prevalent, including genital prolapse in women. The lifetime risk for American women undergoing surgery for pelvic organ prolapse (POP) and urinary incontinence has been reported to be around 11% to 12% [1, 2]. For severe, symptomatic POP, surgery is the preferred treatment to restore normal anatomy, preserve sexual function, and maintain lower urinary tract and bowel function. Anterior and posterior colporrhaphy with or without concomitant vaginal hysterectomy is the standard procedure for correcting prolapse of the anterior and posterior compartments. However, it carries a high risk of failure; in one study, 29.2% of women required further surgery because of recurrence [1]. The reported success rate for anterior colporrhaphy alone varies widely, from 37% to 100% [3].

Factors that contribute to recurrence include weakened native tissue, improper procedures, poor surgical experience, and poor postoperative healing. To reduce the risks associated with host tissue factors, surgeons have turned to

a number of biological and synthetic prosthetic implants, including autologous, allogenic, xenogenic, and synthetic grafts. To date, none has been shown to be ideal. Incisional herniation, the risk of virus or prion transmission, and biological degradation all impose limitations on biological implants. Synthetic meshes may cause erosion, infection, rejection, or de novo dyspareunia. The currently available evidence suggests that type I macroporous, monofilamentous synthetic polypropylene mesh has lower infection and erosion rates than other types, so that some surgeons consider it the prosthesis of choice in pelvic floor reconstructive surgery [4–6].

In addition to the mesh material itself, the design of the prosthesis is important for providing adequate anatomic support. Genital prolapse can occur because of central, lateral, and/or pubourethral defects in the pelvic floor tissues. Procedures that strengthen each of these areas are less likely to fail over time than repairs directed at only one compartment. The new generation of transobturator vaginal mesh design comprises pairs of arms for additional suspension. The extended arms pass through the obturator foramen, fascia, and muscle to reinforce the pubocervical fascia anteriorly and through the ischiorectal fossa and sacrospinous ligament to reinforce the rectovaginal fascia posteriorly.

Transobturator mesh procedures are frequently favored by urogynecologists for repair of advanced POP, although there are no randomized controlled trials comparing such procedures with traditional reconstructive operations. It would, in fact, be very difficult to conduct such a study. In the absence of that type of evidence, it is important to assess the medium- and long-term outcome of mesh procedures. The aim of this study was to evaluate the anatomic and functional outcome of transvaginal pelvic reconstructive surgery using the Prolift technique for POP in women followed for one to 3 years after surgery.

Materials and methods

In this retrospective study, we reviewed the outcome of 65 women with symptomatic POP who underwent transvaginal pelvic floor repair with a total Prolift procedure at Mackay Memorial Hospital, Taipei, Taiwan between October 2005 and August 2008. We excluded women with genital malignancies diagnosed prior to or after surgery or those with neurogenic bladder dysfunction. All women gave informed consent for the procedure using the Prolift™ Pelvic Repair System (Ethicon, Sommerville, NJ, USA). This study was approved by the hospital's Institutional Review Board.

Preoperative investigations included a detailed personal history, urinalysis, and pelvic examination with a Sims speculum. The severity of prolapse was measured in the supine position with a full Valsalva maneuver using the Pelvic Organ Prolapse Quantification system (POP-Q, International Continence Society) [7]. Only women with a POP-Q stage of 2 or greater were included in the study. A complete multi-channel urodynamic study (UDS) was also performed before surgery to evaluate bladder function. The UDS included free uroflowmetry, filling cystometry with stress test at an infusion rate of 80 ml/min, voiding cystometry, and urethral pressure profilometry. The data was analyzed using Medical Measurement Systems UD-2000 (Enschede, the Netherlands). For patients who desired preservation of the uterus, gynecological ultrasound was performed to rule out uterine pathology.

All surgeries were carried out under general anesthesia with intubation or under spinal anesthesia, depending on the patient's condition and preferences. One gram of cefmetazole was given intravenously in the operating room just prior to surgery and for 2 days postoperatively as prophylaxis. If the uterus was to be preserved, uterine sounding with a probe (Taiyu, Japan) was performed. The Prolift procedure was carried out as previously described [8, 9]. Briefly, the anterior part of the mesh was positioned between the bladder and vagina with two pairs of arms passing through the obturator foramen, fascia, and muscles as free of tension as possible. The posterior part was placed between the rectum and vagina and fixed by arms passing through the ischiorectal fossa and sacrospinous ligaments on each side. The mesh was positioned and adjusted so as to be as flat as possible, without any folds. In women who had vaginal vault prolapse or who underwent concomitant hysterectomy, the entire Prolift mesh was kept intact to provide apical support. For those who underwent uterine-sparing reconstructive surgery, the intermediate portion was cut. If an elongated cervix had been detected on preoperative ultrasound and uterine sounding was greater than 10 cm, partial trachelectomy was also performed. The vaginal mucosa was not trimmed. Continuous absorbable 1–0 Vicryl sutures (Ethicon, Sommerville, NJ, USA) were used for closure of the colpotomy. Furacin-soaked gauze was packed in the vagina for 3 days. The skin incisions where the arms of the Prolift mesh were inserted were approximated by Steri-Strip tapes (3M Health Care, USA). Finally, a suprapubic catheter was inserted for postoperative bladder drainage.

Once the vaginal packing was removed, spontaneous voiding was attempted. If the woman was able to void twice successively with a pre-micturition bladder volume of more than 200 ml and a postvoid residual of less than 100 ml, the catheter was removed, and the patient was discharged. Postoperative urinary retention was defined as a postvoid residual of more than 100 ml for more than 14 days [10]. Bladder outlet obstruction was defined on

Table 1 Baseline demographics, prior surgical history, and minor concomitant procedures among 65 women undergoing Prolift technique

Baseline demographics	
Age (mean±SD)	61.2±11.4 years (33–85)
Parity (mean±SD)	3.3±1.6 (1–10)
BMI (mean±SD)	24.8±3.6 kg/m^2
Menopausal status	53 (82%)
Previous surgical history	*N* (%)
Abdominal hysterectomy	13 (20)
Vaginal hysterectomy+SSVS+APR	2 (3)
Rectal surgery	1 (2)
Minor procedures concomitant with Prolift surgery	*N* (%)
Partial trachelectomy[a]	4 (6)
Kelly plication	4 (6)
High ligation of enterocele herniation sac	12 (18)

SSVS supraspinous vaginal suspension, *APR* anterior and posterior colporrhaphies

[a] The cervix was partially excised for those who had elongated cervix or cervical hypertrophy

UDS as a Qmax of less than 12 ml/s and $P_{\text{det. Qmax}}$ over 50 cm H_2O with significant residual urine detected [11].

The intraoperative data collected include estimated blood loss, operative duration, and surgery-related complications. After discharge, postoperative follow-up visits were arranged at 3 and 6 months after surgery and then every 6 to 12 months. At 6 months after surgery, the women underwent full postoperative investigations that resembled the preoperative workup. The POP-Q stage was measured at each follow-up visit and conducted by the same surgeon (the corresponding author). The urodynamic study was carried out by the same third-party technician to reduce possible bias. Postoperative complications were also recorded.

Anatomical failure was defined as a postoperative POP-Q stage 2 or greater. The functional outcome was evaluated by using the short form of the Urogenital Distress Inventory (UDI-6) and the Incontinence Impact Questionnaire (IIQ-7) preoperatively and at 6 months after surgery.

Data are expressed as mean±standard deviation. Wilcoxon signed rank test was used for within-group comparison of variables. Between-group comparisons were performed by using Mann–Whitney *U* test. The data analysis was performed by using SPSS 12.0 for Windows (SPSS, Inc, Chicago, IL, USA). A p value less than 0.05 was considered statistically significant.

Results

The mean age of the 65 women in this study was 61.2±11.4 years (range 33 to 85), mean parity was 3.3±1.6 (range 1 to 10), and mean body mass index was 24.8±3.6 kg/m^2. The length of follow-up ranged from 13 to 35 months with a median of 24.5 months. Eighty-two percent of the subjects (53 out of 65) were postmenopausal.

The operative duration ranged from 33 to 120 min (mean 90±23 min), and the mean blood loss was 344±170 ml (range 50 to 800 ml). Postoperative bladder drainage was required for a mean of 4.7±4.5 days (range 1 to 25 days). The median hospital stay was 8 days (range 5 to 18 days). Fifty women (77%) had uterine prolapse and cystorectocele and the other 15 (23%) had vaginal vault prolapse and cystorectocele. Major procedures concomitant with the Prolift repair included vaginal hysterectomy in 39 (19 for leiomyomata or adenomyosis and the other 20 choosing not to preserve their uterus after discussing the procedure with the surgeon), vault suspension in 15 (13 of whom previously had a hysterectomy and two for recurrent apical prolapse after a previous POP procedure), and hysteropexy in the 11 who wished to preserve the uterus. Sixteen women had previously surgical procedures, and minor additional procedures, including partial trachelectomy, Kelly plication, and hernia sac ligation, were performed in 20 (Table 1).

The preoperative POP-Q stage was 2 in 19 (29%), 3 in 31 (48%), and 4 in 15 (23%). Two patients had recurrent prolapse of the anterior compartment, with POP-Q stage 2 on examination 30 and 32 months postoperatively (Fig. 1). The anatomic success rate for all 65 subjects was therefore

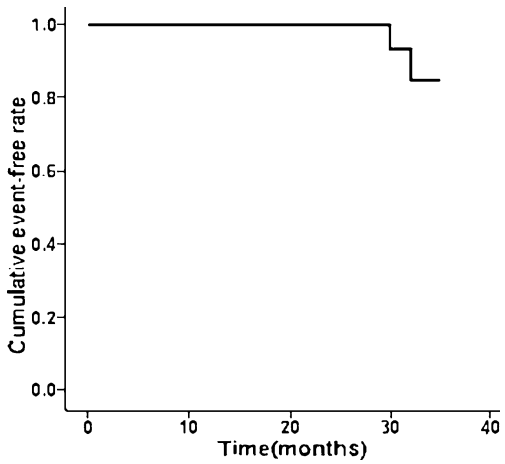

Fig. 1 Event-free survival. Kaplan–Meier survival curve of all subjects undergone Prolift surgery

Table 2 Pre- and postoperative POP-Q point scores in women followed for more or less than 2 years

Points	Followed for over 2 years (*N*=34)			Followed for 1–2 years (*N*=31)			
	Pre-op	Post-op	p^a	Pre-op	Post-op	p^a	p^b
Aa	1.9±1.5	−2.8±0.5	<0.001	1.7±1.4	−3.0±0	<0.001	0.784
Ba	2.9±2.2	−2.7±0.7	<0.001	2.7±2.3	−3.0±0	<0.001	0.995
C	2.5±2.7	−6.8±1.7	<0.001	2.5±3.0	−7.1±1.1	<0.001	0.556
Ap	0.9±1.4	−2.9±0.1	<0.001	0.8±1.3	−3.0±0	<0.001	0.626
Bp	1.7±2.4	−2.9±0.1	<0.001	1.3±2.3	−3.0±0	<0.001	0.763
D	1.2±3.1	−7.0±1.3	<0.001	0.7±2.9	−7.1±1.0	<0.001	0.923
Gh	3.7±1.0	2.5±0.4	<0.001	3.7±1.0	2.4±0.4	<0.001	0.298
Pb	2.2±0.5	2.7±0.7	<0.001	2.4±0.8	2.7±0.5	0.141	0.188
TVL	7.6±0.5	7.3±0.6	0.061	7.3±0.8	7.3±0.5	0.79	0.203

POP-Q Pelvic Organ Prolapse Quantification system, *Aa* point of anterior vaginal wall 3 cm proximal to external urethral meatus, *Ba* point of most distal position of upper anterior vaginal wall, *C* point of either the most distal edge of cervix or leading edge of vaginal cuff, *Ap* point of posterior vaginal wall 3 cm proximal to hymen, *Bp* point of most distal position of upper posterior vaginal wall, *D* point of the location of posterior fornix, *Gh* genital hiatus, *Pb* perineal body, *TVL* total vaginal length

[a] Within group comparison with Wilcoxon singed rank test

[b] Between groups comparison of differences of post- and preoperative values with Mann–Whitney *U* test

97%, while for the 34 women followed for more than 2 years, it was 94%. Both women with recurrence were over 70 years old. However, the difference in success rate between the 19 women over age 70 and the 46 women younger than 70 was not statistically significant (89% vs. 100%, p=0.07). The mean postoperative POP-Q measurements were significantly improved overall compared to preoperative values. The improvement seen in the 34 women followed for more than 2 years was not inferior to that compared with the 31 followed for 1 to 2 years (Table 2), indicating that the improvement achieved by this procedure was relatively durable for more than 2 years after surgery. Of the two women who had late failure (i.e., POP-Q stage 2 on follow-up), one had also undergone vaginal hysterectomy and one vault suspension. The success rate for each group according to surgical procedures was shown in Table 3. Quality of life was significantly improved at 6 months postoperatively as shown by improvement in UDI-6 and IIQ-7 scores. The improvement was statistically significant for women followed for more than 2 years as well as those followed for 1 to 2 years postoperatively (Table 4), although the formal evaluation was only done at 6 months after surgery.

Intraoperative complications occurred in two patients (3%), one with a bladder perforation repaired immediately and one with a bowel perforation and stool leakage that was detected and repaired 3 days after the pelvic surgery. That woman previously had rectal surgery, and the bowel injury apparently occurred in the course of vaginal hysterectomy with lysis of adhesions. Eight patients received a blood

Table 3 The success rate and POP-Q staging before and after operations concomitant with Prolift pelvic floor reconstruction in each group according to surgical procedures (*N*=65)

Surgical procedure	Prolift with hysterectomy (*N*=39)		Prolift with vault suspension (*N*=15)		Prolift with hysteropexy[a] (*N*=11)		Total (*N*=65)	
	Pre-op	Post-op	Pre-op	Post-op	Pre-op	Post-op	Pre-op	Post-op
Stage 0	0	38	0	14	0	10	0	62
1	0	0	0	0	0	1	0	1
2	8	1	5	1	6	0	19	2
3	20	0	6	0	5	0	31	0
4	11	0	4	0	0	0	15	0
Success rate		97%		93%		100%		97%

All patients underwent concomitant anterior and posterior colporrhaphies

Pre-op preoperative, *Post-op* postoperative

[a] Four patients also underwent partial trachelectomy

Table 4 Symptom scores before and 6 months after Prolift reconstructive pelvic floor surgery

	Followed over 2 years (N=34)			Followed for 1–2 years (N=31)			
	Pre-op	Post-op	p^a	Pre-op	Post-op	p^a	p^b
UDI-6	5.6±4.2	2.1±2.4	<0.001	5.5±4.1	2.5±2.5	0.001	0.331
IIQ-7	8.1±6.4	2.6±4.9	<0.001	6.3±5.7	2.0±4.1	<0.001	0.330

UDI-6 short form of the Urogenital Distress Inventory Questionnaire, *IIQ-7* short form of the Incontinence Impact Questionnaire

[a] Within group comparison with Wilcoxon singed rank test

[b] Between-group comparison of differences of post- and preoperative values with Mann–Whitney *U* test

transfusion intra- or postoperatively, and six of whom underwent vaginal hysterectomy because of leiomyoma. Those women had a bigger and heavier uterus than those undergoing the same surgery without the need for transfusion (the greatest dimension of uterine corpus, 11.5±2.2 cm vs. 7.9±1.8 cm, $p<0.001$; uterine weight, 173.1±113.6 g vs. 59.9±37.8 g, $p<0.001$).

Postoperatively, there was one vaginal hematoma in the posterior wall detected during hospitalization; it resolved with conservative management. One woman presented pelvic pain, tenderness, and fever with leukocytosis 2 weeks after surgery. Pelvic infection was confirmed by the result of culture (*Enterococcus* species). She was readmitted and treated by antibiotics with good response. One patient had a mesh erosion that developed 2 months after the operation. It did not respond to treatment with estrogen cream and therefore required local excision and primary closure of the wound. Postoperative urinary retention occurred in four women (6%), with spontaneous resolution in three (ranging from 15 to 25 days after surgery). Transurethral dilatation with Hegar dilators performed in the fourth case. These four women had no subsequent voiding dysfunction throughout follow-up. Four others developed postoperative voiding symptoms, one woman with de novo bladder outlet obstruction not present on preoperative UDS but found during follow-up UDS, and three women (5%) with de novo detrusor overactivity.

Discussion

As far as we are aware, there is limited data of the outcome of pelvic floor reconstructive surgery with Prolift for POP after 2 years' follow-up in the English literature. Two years is considered the minimal postoperative follow-up for evaluating the outcome of pelvic floor reconstructive surgery [12], and slightly over half of our patients were followed for more than 2 years. The anatomical success rate was 97% among all 65 women (all followed for at least 1 year) and 94% for the 34 women followed for more than 2 years. These figures compare very favorably with other studies which report a cure rate between 86.6% and 100% at two to 19 months of follow-up [8, 13–19]. They are also appear to be better than other investigations with a minimum 1 year follow-up (92.3% to 86.6%) [13, 15, 18, 19]. A possible explanation for our excellent results is the fact that we chose to repair all compartments using the total Prolift repair system. There is still controversy as to whether all compartments should be repaired during POP surgery. Dwyer et al. [20] reported a 7% incidence of de novo prolapse in women who initially had repair of only one compartment with mesh. Benson et al. [21] earlier suggested repair of all compartments, although they were comparing abdominal with vaginal procedures before the use of mesh repair.

Uterine-sparing reconstructive operations in our series were successful in all 11 cases except in one patient who had asymptomatic stage 1 anterior prolapse postoperatively. These results are consistent with those of Vita et al., reporting a 100% cure rate with a uterine-sparing technique using polypropylene mesh [22]. It should be noted that four of our patients also underwent partial trachelectomy, as our previous experienced demonstrated that this is useful in preventing recurrent prolapse in women with an elongated cervix [23]. Both women in whom the Prolift procedure failed had stage 3 prolapse preoperatively and a recurrent stage 2 cystocele postoperatively. In a review of anterior repair, Maher and Baessler noted that cystocele is a common recurrent problem after prolapse surgery [6]. None of our patients had recurrent apical prolapse, suggesting that the total Prolift system provides excellent apical compartment support. But even with adjuvant transvaginal meshes, cystocele is the most likely recurrent compartment.

Interestingly, both of our patients who had anatomic failure were older, with stage 3 prolapse preoperatively. Whiteside et al., on the other hand, indicated that younger patients with advanced prolapse are more likely to experience recurrence after a vaginal repair procedure [24]. Our numbers were too small to find a statistically significant difference between women older and younger than 70, but this issue would worth be exploring with larger studies.

Mesh erosion is one of the major shortcomings of this type of pelvic floor reconstructive surgery, with a reported incidence ranging from 4.7% to 10% [8, 13–18]. This complication fortunately occurred in only one of our patients. Although type I synthetic polypropylene mesh has a lower potential for erosion than other types used in transvaginal repair surgery [4–6], it is important to pay careful attention to flattening the mesh to avoid folds, minimize or eliminate trimming of the vaginal wall, and avoid vaginal dissection along too superficial a plane. We believe this careful surgical technique reduces the risk of erosion. Similar concern should be paid to avoiding infection, which also occurred in only one woman in our series. This is an acceptable complication rate for a foreign body implant as mesh, but no infections would be even better! Prophylactic antibiotics, adequate postoperative vaginal packing to achieve hemostasis, and aseptic procedures are, we are convinced, important actions for preventing mesh-related infection.

In our series, 12% (8 of 65) required blood transfusion after the Prolift procedure. In five cases, intraoperative blood loss was over 500 ml. There are two possible reasons that the percentage of women requiring transfusion in our series was higher than that reported by others [14, 25]. First, hydrodissection with vasoconstrictive agents was not used during the operation procedures. Second, six of the eight women requiring transfusion simultaneously underwent total vaginal hysterectomy for large leimyomata. They had significantly larger and heavier uteri, requiring maceration to remove the organ vaginally. Major blood loss thus was a problem primarily associated with hysterectomy.

Although serious complications are uncommon during Prolift surgery, there certainly are reports of injury to visceral organs. We had two in this series, a bladder injury detected intraoperatively during lateral dissection and bowel perforation. In the latter case, the complication did not appear to be secondary to the Prolift procedure itself but rather to the vaginal hysterectomy in a patient with pelvic adhesions from prior rectal surgery.

Resumption of normal voiding was the norm in our series, with only four women having clinically significant postoperative urinary retention. This resolved with conservative management in three. However, there were three cases of de novo detrusor overactivity and one of bladder outlet obstruction noted on follow-up. Although the Prolift operation is designed as a tension-free procedure, there is still no simple method to guarantee precise adjustment of the mesh to avoid all tension. Our experience certainly demonstrates that this procedure provides good support and, for most women, improvement in lower urinary tract symptoms, as evidenced by the significantly improved UDI-6 and IIQ-7 scores postoperatively. However, the possibility remains that some women will develop new symptoms of lower urinary tract dysfunction and patients should be monitored for such symptoms as part of routine follow-up. The reported incidence of dyspareunia after insertion of synthetic mesh ranges from 0% to 69% [6, 26]. We have previously published a study of sexual function after the Prolift procedure in which we found that 73% of sexually active patients reported deterioration in sexual function (not necessarily dyspareunia) 6 months after the procedure [27].

Our study has several limitations. There was no control group for comparison. In addition, various procedures in addition to Prolift were performed, although the data does not suggest marked differences by specific procedure (Table 3). As noted above, only half of our patients had been followed for two or more years postoperatively, but the outcome in those patients was similar to that of those followed for less than 2 years. We demonstrated not only that the Prolift procedure was successful with a low rate of complications but also that these good results appear to be durable even beyond 2 years. These questions should be revisited as larger pools of patients are followed for longer periods of time.

In conclusion, in our hands, POP reconstructive surgery using the Prolift™ system yielded an anatomical cure rate of 97% after a median of 2 years of follow-up (94% in those followed for more than 2 years). The complication rate was acceptable, and postoperative quality of life was good, according to the symptom questionnaires we used. Only with time can longer term results be evaluated.

Conflicts of interest None.

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