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Synthetic Graft Use in Vaginal Prolapse Surgery: Objective and Subjective Outcomes

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Abstract

Introduction—This study reports one year outcomes in women who underwent transvaginal pelvic organ prolapse (POP) surgery with Prolift[®] transvaginal mesh.

Methods—Pre and post-operative objective vaginal (Pelvic Organ Prolapse Quantification, POP-Q) and subjective symptom and impact assessments (Pelvic Floor Distress Inventory-20, PFDI-20; Pelvic Floor Impact Questionnaire-7, PFIQ-7, respectively) were performed. Post-operative vaginal tenderness, stricture and patient satisfaction were also obtained. Paired t-tests were utilized for analysis.

Results—Mean age was 61.8±9.8 years; mean follow-up interval was 425.0±80.0 days (range: 237–717). POP-Q measurements of Ba, Bp, and C were significantly improved (all p-values <0.001). PFDI and PFIQ subscale scores significantly improved (all p-values ≤0.004). Thirty-five of 48 (73%) were completely satisfied, 2 (4%) were not satisfied. Complications [n(%)] included graft exposure [1(2%)], dyspareunia [2(4%)], and granulation tissue [3(6%)].

Conclusions—Women undergoing transvaginal repair of POP with the Prolift[®] mesh system showed significant improvement in one-year anatomic and subjective measures.

Keywords

Pelvic organ prolapse; surgery; Prolift[®] mesh; graft; outcomes

Introduction

Pelvic organ prolapse (POP) is a prevalent condition with over 200,000 surgeries performed yearly [1]. This is not surprising considering that 4.1% of American women have been found to have prolapse beyond the hymenal ring [2]. Traditional surgical techniques for the treatment of POP have involved a suture repair with tissue plication/colporrhaphy. Improvement in outcomes of these procedures has been desirable as historically they have a high rate of recurrence; as many as one third of women are reported to have needed repeat

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surgery [3, 4]. This has led to a demand for innovation and a call for the development of a more durable surgical treatment approach which has resulted in the use of graft materials to augment traditional repairs. The grafts may serve as a scaffold or bridge to allow native tissue to grow, subsequently adding reinforcement and strength to a repair [5].

The Prolift® (Ethicon, Somerville, NJ, USA) polypropylene mesh is one such synthetic graft kit that has become increasingly popular. The Prolift® kit utilizes a trocar based delivery system with a synthetic macroporous monofilament polypropylene mesh. A dearth of long term efficacy and safety data regarding its use in transvaginal prolapse surgery exists. The aim of this study is to report prospective objective and subjective outcomes one year post-operatively in patients who have undergone a trans-vaginal approach for the treatment of pelvic organ prolapse with Prolift® graft augmentation.

Materials and Methods

Institutional Review Board approval was obtained at the University of Alabama at Birmingham. Sixty-eight consecutive patients who had undergone a transvaginal surgical approach for the treatment of pelvic organ prolapse with the Prolift® system from July 1, 2006 to June 30, 2007 were identified. Patients had undergone either an anterior, a posterior, or an anterior and posterior (total) Prolift®. The decision on the type of Prolift® utilized and concomitant procedures planned were based upon clinical judgment of the staff surgeon. All patients undergoing a Prolift® procedure had expressed desire for future vaginal sexual function.

All patients completed questionnaires pre-operatively. Study patients were contacted via US mail and follow-up telephone call. Patients agreeing to participate in the study were scheduled for a one- year post-operative clinic visit.

The post-operative physical examination was performed by a clinician not involved in the patient's care, using the Pelvic Organ Prolapse Quantification (POP-Q) technique [6]. A systematic examination for pain and stricture formation was performed. Pain was defined as any noted vaginal tenderness during bimanual examination in the anterior or posterior vaginal walls classified from the introitus to -3 cm, from -3cm to -6cm, and from -6 cm to the vaginal cuff. A stricture was defined as a restrictive vaginal band noted on bimanual vaginal examination. Post-operative physical examination findings were compared to pre-operatively collected data.

Patients completed subjective symptom specific baseline validated questionnaires both prior to surgery and again at the one-year post-operative visit. The questionnaires included the short forms of the Pelvic Floor Distress Inventory (PFDI-20) [7], the Pelvic Floor Impact Questionnaire (PFIQ-7) [7], and the Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire (PISQ)[8]. Post- operative satisfaction was assessed via the Patient Satisfaction Questionnaire (PSQ) [9]. A chart review revealed pertinent demographic data including age, race, parity, medical conditions, and history of previous surgery.

Operative and post-operative notes were reviewed to evaluate complications. Intra-operative complications were defined as blood loss greater than 1000cc, bladder injury/perforation, or bowel perforation. Post-operative complications included infection, fever, urinary tract infections, dyspareunia, pain, neuropathy, mesh exposure, the formation of granulation tissue, or tenderness/stricture formation.

Questionnaires were scored according to published protocols [7,8,9]. Statistical analysis was performed using paired t-tests comparing pre- and post-operative data using JMP® Statistical software (SAS, Cary, NC, USA).

Results

Sixty-eight patients underwent POP repair with the Prolift® system from July 2006 through June 2007. At least one- year follow-up data was obtained on 50 out of 68 women (74%) who had undergone a Prolift® procedure during that time. Eighteen of the 50 women underwent placement of a total, 16 underwent placement of a posterior, and 16 women underwent placement of the anterior Prolift® transvaginal polypropylene mesh placement.

The mean± SD age, BMI and parity were 61.8±9.8 years, 29.4±6.1 kg/m², and parity was 2.7±1.3, respectively. Subjects were assessed at a mean±SD follow-up of 425.0±80.0 days (range 237–717). Previous prolapse surgery had been performed on 40% of participants (n=20). Mean pre-op post- void residual was 59.15±69.31 and mean POP-Q pre-op stage was 2.67±0.77 (median 3, range 1–4). Complete demographic information is presented in Table 1.

Demographic comparison between patients who followed up and those who failed to follow up are reported in Table 1. Non-responders were more likely to have diabetes mellitus (p=.03) and reported more severe pre-operative subjective urinary incontinence bother on the UIQ questionnaire (p=.02).

For participants, concomitant surgery included anterior repair (n=36), posterior repair (n=42), enterocele repair (n=22), retropubic midurethral sling (n=29), trans-obturator midurethral sling (n=1), vaginal hysterectomy (n=3), and intra-peritoneal vaginal vault suspension (n=33).

Objective outcomes are reported in Table 2. At one year post-operatively, POP-Q measurements of Ba, Bp, and C were significantly improved from baseline (p<0.001). Mean change in Ba was 2.8±3.3, mean change in Bp was 2.4±3.5, and mean change in C was 3.7±6.6. Overall improvement was noted in POP- Q stage. Pre-operatively, 61.2 % of patients had stage 3 or 4 prolapse. At one year postop, only 1 patient (2.2%) had stage 3 or 4 prolapse. Mean pre-op PVR was 59.14±69.31 (n=47). Mean post-op PVR was 71.88±95.19 (n=45).

Vaginal tenderness and stricture was assessed at different sites measured from the hymenal ring at one year post-op follow-up. From the introitus to –3 cm, 2 participants experienced anterior tenderness (1 participant had undergone a posterior Prolift®, one an anterior Prolift®), 2 experienced posterior tenderness (1 posterior and 1 anterior Prolift®), and 1 participant had circumferential tenderness (1 posterior Prolift®). One anterior stricture was noted. From –3cm to –6cm, 1 circumferential tenderness (posterior Prolift®) was noted and no cases of stricture were identified. From –6 cm to the vaginal cuff, 2 anterior (1 total and 1 anterior Prolift®) and 2 circumferential (1 posterior and 1 anterior Prolift®) cases of tenderness were noted and no strictures were identified.

Subjective outcomes are reported in Table 2. There was significant improvement seen on all subscales of the Pelvic Floor Distress Inventory. Improvement was also noted on the UIQ and POPIQ portions of the Pelvic Floor Impact Questionnaire. Overall, significant improvement was noted in quality of life scores. Based on 10 patients, PISQ scores did not change after surgery (p=0.082). Patient satisfaction scores (n= 48) demonstrated 73% of patients were completely satisfied, 23% were somewhat satisfied, and 4% were not satisfied. Fifty-seven percent of patients rated their improvement in *symptoms* as “Very Much Better,” 69% rated their *overall* improvement as “Much Better” (n=48). No significant impact on sexual function was noted.

Average blood loss for placement of either type of Prolift® was 104.5±67.9cc. No patients required intra-operative or post-operative blood transfusions, and no procedure had an estimated blood loss of greater than 1000cc. No bowel injuries were identified. Bladder injuries occurred in 2 participants undergoing anterior Prolift® placement. One patient had a puncture sites noted at the time of cystoscopy without evidence of mesh in the bladder; no intervention was necessary. The second patient sustained an incidental cystotomy at the time of anterior dissection, likely secondary to adhesions from previous anterior repair. This was surgically repaired and the mesh was placed without complication.

Immediate post-operative complications included re-admission for fever 2% (n=1), dyspareunia 4% (n=2), and pain 12% (n=6). Post-operative pain was largely characterized as groin pain. Neuralgia where the patient manifested with minimal incisional pain was identified in 1 participant who had undergone an anterior Prolift® (2%). Mesh exposure was identified in 1 (2%) patient which required subsequent excision. Two participants reported serosanguinous vaginal discharge (4%). Granulation tissue was identified in 3 participants (6%) Tenderness over the graft at the postoperative visit was identified in 6 participants (12%).

Discussion

In this study, overall improvement was noted in individual POP-Q anatomic points and POP-Q stage at one year. Only one patient (2%) was identified as having failed and subsequently underwent a laparoscopic sacrocolpopexy during the one year follow-up period. Our findings are consistent with other investigators. Altman et al reported outcomes at 2 months following anterior repair, posterior repair, both individually repaired or total repair with Prolift® with success rates of 87%, 91%, and 88% respectively [3]. Fatton et al reported outcomes at 3 months, reporting a short term failure rate of 4.7% and recurrence rate of 3.7% [10]. Similarly, a study by Van Raalte et al evaluated 97 patients in a retrospective study measuring pre- and post-operative outcomes at one year in patients who underwent placement of the Prolift for post-hysterectomy prolapse with a median follow-up of 19 months. Lower urinary tract and other pelvic floor symptoms as well as impact on quality of life were reported utilizing the Incontinence Impact Questionnaire (IIQ-7) and the Urogenital Distress Inventory (UDI-6). Anatomic success defined as stage 1 or less prolapse in the treated compartment based upon the POP-Q system was noted to be 86.6% in those participants evaluated at one year or greater follow-up [11]. Despite these early reports, longer-term studies are needed to evaluate sustainability of safety, anatomic and functional outcomes.

The Prolift® system incorporates a transobturator approach through the arcus tendineus fascia pelvis, as well as a transgluteal approach through the sacrospinous ligaments. The safety of this technique with regard to peri-operative morbidity has been previously reported. A longer term follow-up study by Altman et al., evaluated safety in a study that involved 248 women during a 6 month time period. They reported the rate of serious complications, defined as visceral injury and estimated blood loss greater than 1,000ml, as 4.4%. Minor complications, defined as urinary tract infections, urinary retention, and post-operative fever occurred in 14.5% of patients [12]. In the study by Fatton et al, 110 patients were seen at 3 months. The rate of granulation tissue formation was 2.8% and mesh exposure was 4.7%. The rate of immediate post-op complications including UTI, urinary retention, abscess and hematoma formation was 1.8% [10]. In our study, major operative complications, defined as visceral injury, intra-op or post-op blood transfusions, or estimated blood loss greater than 1000cc occurred at a similar rate of 4%. In order to minimize the risk of post-operative mesh exposure/erosion, our patients were prescribed pre and post-operative vaginal estrogen cream. Intra-operative technique included a

hydrodistention-aided dissection in order to gain access to the true vesico and recto-vaginal spaces.

In our study, placement of the Prolift® graft appeared to have no significant positive or negative impact on sexual function based upon reports of dyspareunia and evaluation of the PISQ. The rate of dyspareunia reported in our study was 4%. However, a significant portion of our patients were not sexually active before surgery and the PISQ analysis was limited to 10 participants. A study by Lowman et al reported de-novo dyspareunia as high as 16.7%. However, most patients in that study stated that they would have the procedure performed again [13]. This finding emphasizes the complex psychosocial and physiologic components involved in sexual function.

There are several strengths to our study. Post-operative physical examinations were performed by clinicians blinded to the operative intervention. We utilized validated symptom specific subjective outcomes questionnaires both pre and post-operatively allowing for meaningful comparisons. We also attempted to measure the delayed mesh complication associated with tissue contracture. This was performed in a formal, defined fashion from the vaginal hymen to a point 3 cm proximal, from this point to 6 cm proximal to the hymen and then from this point to the apex. Only one case of vaginal stricture was noted, however there were 10 cases of associated vaginal tenderness by patient self-report. There are no validated tools to measure these findings, yet the occurrence of tissue contracture can significantly impact on vaginal function. Furthermore, all cases from the reporting institution of this procedure are reported, thus encompassing the procedural learning curve, making these findings applicable to other surgeons.

The major limitation of our study is incomplete patient follow-up. Our institution is a regional referral center with patients from across the Southeastern United States. Travel was a barrier to follow-up for several patients. The analysis comparing participants to non-responders showed few demographic differences, none of which would suggest inferior outcomes in the non-responders. Diabetes was more prevalent in the non-responders, conceivably increasing infection risk. We would have expected these patients to present for follow-up specialty care if infection was present. An additional limitation was the lack of a standardized pre-operative pain assessment.

In our study, high patient satisfaction and improvements in quality of life measures were noted. Objective improvements, previously only studied in short term follow-up, were sustained at one year post-op. Minimal complications were also noted. Based on our study, the Prolift® system appears to be a safe and effective transvaginal method of facilitating the repair of pelvic organ prolapse. Longer term outcome surveillance, however needs to be performed to further understand later onset complications which may occur, as well as risk for prolapse recurrence.

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Abbreviations

POP Pelvic Organ Prolapse

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Table 1

Patient Demographics

	1 year follow-up (N=50)	Nonresponders/failed to follow-up (N=18)	p-value
Age (y)	61.8±9.8	57.0±8.4	0.071
BMI (kg/m ²)*	29.4± 6.1	30.0±6.7	0.760
Parity	2.7± 1.3	2.8±1.9	0.741
Race			0.265
White	50(100)	17(94.4)	
Other	0	1(5.6)	
Tobacco	7(14)	3(16)	0.784
Menopausal	46(92)	16(89)	0.506
DM	4(8)	5(27.8)	0.034
HTN	26(52)	13(72)	0.137
Asthma	5(10)	2(11)	0.894
Previous Prolapse Surgery	20(40)	6(33)	
Previous Anterior Repair	16(32)	3(17)	0.214
Previous Posterior Repair	13(26)	3(17)	0.423
Previous Paravaginal Repair	7(14)	2(11)	0.757
Previous Hysterectomy	45(90)	13(72)	0.068
Pre-op POP-Q Stage	2.67±0.77	2.9±.44	0.220

Mean ± SD; N(%)

Table 2

Subjective and Objective Outcomes

POP-Q Stage *	Pre-operative	Post-operative	Change	p- value
Stage 0	0	10.9 (5)	-	-
Stage 1	4.1 (2)	41.3 (19)	-	-
Stage 2	34.7 (17)	45.6 (21)	-	-
Stage 3	49.0 (24)	0	-	-
Stage 4	12.2 (6)	2.2 (1)	-	-
Overall **	3, 1–4	1, 0–4		
Ba ***	+1.1±3.3 (48)	−1.5±1.8 (46)	2.8±3.3 (44)	<0.001
Bp	0.2 ± 2.8 (47)	−2.2±1.7 (46)	2.4±3.5 (44)	<0.001
C	−2.2± 5.6 (47)	−6.7±4.5 (46)	3.7±6.6 (44)	<0.001
TVL	8.8±3.0 (33)	7.9±2.9 (45)	−1.1±4.8 (29)	0.243
GH	4.8±1.3 (42)	3.0±1.1 (46)	1.9±1.4 (39)	<0.001
PB	3.5±1.2 (42)	3.9±1.2 (46)	−0.3±1.6 (39)	0.197
PFIQ ***				
UIQ	32.0±29.8 (41)	13.7±23.9 (50)	−19.1±27.5 (41)	<0.001
CRAIQ	23.9±27.4 (34)	8.8 ±17.2 (50)	−15.9±29.9 (33)	0.004
POPIQ	33.2±33.4 (34)	9.8±21.5 (50)	−21.6±28.9 (33)	<0.001
PFDI: ***				
UDI	50.5 28.9 (40)	22.9±21.4 (50)	−28.5±23.0 (40)	<0.001
CRADI	39.3 27.0 (34)	22.3±20.8 (50)	−17.6±24.6 (33)	<0.001
POPDI	61.3±24.1 (34)	14.2±17.6 (50)	−47.7±25.7 (34)	<0.001
PISQ ***	20.2±4.9 (10)	16.2±6.0 (23)	−3.2±5.1	0.084

*
% (N)**
median, range***
Mean ± SD (N)