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Synthetic Graft Augmentation in Vaginal Prolapse Surgery: Long-term Objective and Subjective Outcomes

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Abstract

Objective—To report long-term objective and subjective outcomes of women who have undergone prolapse surgery with a synthetic graft augmentation.

Design—Retrospective analysis

Design Class—Canadian Task Force classification II-3

Setting—An university hospital in southeastern United States.

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Patients—Women with symptomatic pelvic organ prolapse who underwent transvaginal graft augmentation using the Prolift™ system between July 2006 and December 2008 for a minimum of 5 year follow-up.

Interventions—Subjects completed the Pelvic Floor Distress Inventory (PFDI-20), the Pelvic Floor Impact Questionnaire (PFIQ-7), the Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire (PISQ), and the Patient Satisfaction Questionnaire. Subjects also underwent post-operative physical examination with Pelvic Organ Prolapse Quantification (POP-Q) and vaginal pain/stricture assessment. Long-term postoperative findings were compared to preoperative baseline data.

Measurements and main results—Of 208 eligible subjects; 70 completed questionnaires only, and 48/70 provided both postoperative examination and questionnaire data. Mean follow-up interval was 7.0±0.7 (range: 5.8–8.1) years. POP-Q measurements of Ba, Bp, C, GH, PB and overall POP stage significantly improved (all $p<.001$ except for PB, $p=.006$). PFIQ (total, UIQ, POPIQ) and PFDI (total, UDI, POPDI) scores significantly improved (all $p<.001$). No differences were noted in the Colorectal-Anal subscales (CRAIQ, CRADI) and PISQ scores at >5 year follow-up (all $p>.05$). Satisfaction rates were 15.7% not at all, 35.7% somewhat, and 48.6% completely satisfied. Complications [n(%)] included graft exposure [3(6%)] and dyspareunia [25(36%)].

Conclusion—Women undergoing transvaginal prolapse surgery using a synthetic graft continue to have positive objective and subjective outcomes leading to significantly improved quality of life at a minimum of 5 year follow-up.

Keywords

Long term outcomes; mesh; pelvic organ prolapse; prolapse surgery; transvaginal mesh

Introduction

The demand for treatment of pelvic floor disorders, such as pelvic organ prolapse, is estimated to increase by 45% by 2030,[1] and the lifetime risk of a women undergoing prolapse surgery is 13%.[2] In the United States (US), more than 300,000 prolapse surgeries are performed each year.[3] Of these women, recurrence rates associated with traditional native tissue repairs have been reported as high as 58%, and 20–30% will undergo reoperation.[4,5] Given the high recurrence and reoperation rates, increasing demand exists for more durable surgical approaches for pelvic organ prolapse. Transvaginal mesh was introduced as a minimally invasive option to augment the durability of the repair in an attempt to reduce surgical failure. Although the definitions used for ‘cure’ vary among studies, existing data on short- to mid-term follow-up of the efficacy of synthetic graft showed significantly higher objective and equal or better subjective cure rates overall compared to traditional repairs without graft augmentation. However, most existing studies report outcomes based on follow-up of less than 2 years.[6–8] Thus, long-term data on the safety and efficacy of synthetic graft use in vaginal prolapse surgery are very limited.

Although currently off the market, many women underwent Prolift™ (Gynecare, Ethicon, Somerville, NJ, USA) mesh augmentation, and long-term postoperative outcome assessments are relevant and important. We previously reported mid-term outcomes (mean

follow-up 425±80 days) of transvaginal POP surgery using Prolift™ showing significant improvement in subjective symptoms and quality of life, as well as anatomic measurements. [9] The aim of this study is to report long-term (minimum of 5 years follow-up) objective and subjective outcomes of women who have undergone Prolift™ graft augmentation.

Materials and Methods

This is an observational study of women undergoing transvaginal surgical management for the treatment of pelvic organ prolapse using the Prolift™ system between July 1, 2006 and December 31, 2008 at the University of Alabama at Birmingham. Institutional review board approval was obtained. The decision to undergo a transvaginal mesh-augmented repair was mutually made by the patient and her surgeon during preoperative counseling. The decision on the type of Prolift™ and concomitant procedures were based upon clinical judgment of the primary surgeon. Prior to surgery, all patients completed the validated questionnaires including the Pelvic Floor Distress Inventory, the Pelvic Floor Impact Questionnaire, the Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire, [10–12] in addition to physical examination using the Pelvic Organ Prolapse Quantification approach as part of the institution's routine practice in the preoperative assessment. The Pelvic Floor Distress Inventory-20 consists of 3 scales, Urogenital Distress Inventory, Pelvic Organ Prolapse Distress Inventory, and Colorectal-Anal Distress Inventory, each ranging from 0 to 100, with a maximum summary score of 300. The Pelvic Floor Impact Questionnaire-7 also consists of 3 scales, Urinary Impact Questionnaire, Pelvic Organ Prolapse Impact Questionnaire, and Colorectal-Anal Impact Questionnaire, each ranging from 0 to 100 with a maximum summary score of 300. Higher scores of the Pelvic Floor Distress Inventory-20 and Pelvic Floor Impact Questionnaire-7 indicate a greater negative symptom distress and impact on quality of life. The Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire scores range from 0 to 48, with higher scores indicating greater sexual function. [10,11]

All patients who had undergone the surgery during the noted period were contacted via US mail. Subjects agreeing to participate in the study were invited to undergo a postoperative physical examination using the Pelvic Organ Prolapse Quantification system and a systematic examination for vaginal pain/stricture by a clinician not primarily involved in the patient's care. Pain was defined as any tenderness noted in the following vaginal segments during physical examination; the distal (the introitus to –3cm), middle (from –3 to 6 cm), and proximal vagina (from –6 cm to the vaginal cuff). A stricture was defined as a restrictive vaginal band noted on examination. Postoperative physical examination findings were compared to pre-operatively collected baseline data.

Subjective outcomes of pelvic floor symptoms, impact on quality of life, and sexual function at a minimum of 5 year follow-up were assessed using the same validated questionnaires obtained prior to surgery. Subjects' long-term postoperative satisfaction was assessed via the Patient Satisfaction Questionnaire.[12] Postoperative complications including dyspareunia, mesh exposure, pain, and stricture formation were assessed. Demographic data including age, race, parity, medical conditions, and history of previous surgery were obtained by medical record review.

Statistical analyses were performed using the, Mann-Whitney U test, McNemar's test, Fisher's exact test, and paired t-test, and Wilcoxon signed rank test as appropriate. P-values of .05 were considered statistically significant. Statistical analyses were conducted using SAS version 9.3 (SAS Institute, Inc., Cary, NC).

Results

Of 208 eligible subjects, 70 completed postoperative questionnaires only, and 48/70 provided both postoperative examination and questionnaire assessment. The mean follow-up interval was 7.0 ± 0.7 (range, 5.8–8.1) years. Mean age was 60.3 ± 9.3 years. The graft was inserted in the anterior wall in 33 (47%), posterior wall in 23 (33%), and both compartments in 14 (20%) of the identified subjects. Previous surgical history of the subjects is as follows: 83% previous hysterectomy, 33% previous incontinence surgery, 39 % previous anterior repair (transvaginal native tissue repair), 17% previous posterior repair (transvaginal native tissue repair), 9% previous paravaginal surgery. The majority had either stage II (45%) or stage III (45%) prolapse at baseline. Within the stage II group, 29/31 patients had prolapse at or beyond the hymen. Baseline demographic and clinical characteristics of the study population are summarized in Table 1. Further demographic comparison was carried out between patients who followed up in this long-term study and those who did not ("non-responders"). As shown in Table 1, no demographic difference was observed between the study population and the non-responders except for hypertension and the type of Prolift™ used ($p=.03$ and $.003$, respectively, Table 1).

Concomitant surgery included anterior repair ($n=33$), posterior repair ($n=38$), enterocele repair ($n=29$), transvaginal apical suspension (performing either uterosacral or sacrospinous ligament suspension separate from the Prolift™ mesh surgery, $n=43$), transvaginal hysterectomy ($n=8$), and midurethral sling ($n=36$).

Objectively, Pelvic Organ Prolapse Quantification measurements of Ba, Bp, C, GH, PB and overall pelvic organ prolapse stage significantly improved compared to baseline (all $p<.001$ except for PB, $p=.006$, Table 2). All subjects had either stage 1 or 2 prolapse at >5-year follow-up. Only 3 women (6%) had the leading edge of prolapse beyond the hymen.

Subjectively, 56 (80%) women reported the absence of vaginal bulge symptoms at a minimum of 5 year follow-up. When assessing symptom distress and impact on quality of life, the Pelvic Floor Distress Inventory (total, Urogenital Distress Inventory, Pelvic Organ Prolapse Distress Inventory) and Pelvic Floor Impact Questionnaire (total, Urogenital Impact Questionnaire, Pelvic Organ Prolapse Inventory Questionnaire) scores significantly improved (all $p<.001$, Table 2). No difference was noted in the Colorectal Anal Impact Questionnaire or Colorectal Anal Distress Inventory ($p = .29, .11$, respectively, Table 2) and the Pelvic Organ Prolapse/Urinary Incontinence Sexual Function questionnaire scores ($p=.14$, Table 2) at >5 years follow-up.

As the technique of the Prolift™ mesh placement differs among the anterior versus posterior and combined compartments, we further analyzed whether the location and mechanism of the Prolift™ placement affects long-term outcomes. Objectively, the Pelvic Organ Prolapse

Quantification measurements of the corresponding compartments (Ba for the anterior Prolift™, Bp for the posterior Prolift™, both Ba and Bp for the combined Prolift™ group), GH, as well as over-all prolapse stage was significantly improved compared to baseline in all three groups ($p<.05$, Table 3). Apical support (point C) improved in all three groups, however, significant changes were noted only in the anterior and combined groups. Subjectively, the Pelvic Organ Prolapse Distress Inventory and Pelvic Organ Prolapse Inventory Questionnaire scores significantly improved in all three Prolift™ mesh placement approaches ($p<.05$, Table 3). No difference was noted in the Pelvic Organ Prolapse/Urinary Incontinence Sexual Function questionnaire scores at >5 years follow-up ($p=1.0$ anterior, .07 posterior, .50 combined, Table 3), which was consistent with the overall analysis.

Overall dyspareunia was noted in 25 (36%) women. Patient satisfaction scores demonstrated 15.7% not satisfied at all, 35.7% somewhat satisfied, and 48.6% completely satisfied. Three of 70 subjects (4.3%) had undergone surgical revision, 5 (7%) had conservative management (either pessary or pelvic floor muscle training). We also explored the cumulative treatment success rate combining anatomical measures using the hymen as a threshold for objective success, absence of bulge symptoms as subjective success, and no re-treatment. In this study, 70% of the subjects met all three criteria for overall treatment success.

Intraoperative and immediately postoperative (within 6 weeks of surgery) complications include 2 (3%) bladder perforations, 1 (1%) surgical site infection, 2 (3%) fever, and 8 (11%) urinary tract infection. No bowel or other organ injuries, or blood transfusions were observed.

Vaginal tenderness and presence of stricture was also assessed. Tenderness was noted in 4 (8.5%) women in the distal, 5 (10.6%) in the middle, and 12 (25.5%) in the proximal vagina. Vaginal stricture was noted in 1 subject (2.1%) in the proximal vagina after undergoing an anterior Prolift™. Graft exposure was seen in 3/48 (6.4%) subjects examined. All subjects with exposure underwent anterior Prolift™. These subjects had discontinued vaginal estrogen use after surgery and had significant vaginal atrophy noted on examination.

Discussion

Women undergoing transvaginal pelvic organ prolapse surgery using the Prolift™ system continue to have positive outcomes in restoration of anatomy, improved symptom specific distress and impact on quality of life greater than 5 years post-surgical treatment. Most existing data on synthetic mesh augmentation are limited by short- to medium-term follow-up durations, whereas the mean follow-up duration of this study was 7 years.

This study demonstrated that subjects sustained significant improvement in objective prolapse measurements using the Pelvic Organ Prolapse Questionnaire system and stages. All subjects had a prolapse stage of less than or equal to stage 2. When using the hymen as a threshold for treatment success, 94% of the subjects met the anatomical success criteria for prolapse surgery. Similarly, our previous mid-term follow-up data showed 98% of subjects having the leading edge of prolapse above the hymen.[9] The placement approach of the Prolift™ mesh differs among anterior, posterior, and combined Prolift™. Although the

three-group analysis is limited by the small sample size (33 anterior, 23 posterior, 14 combined), significant anatomical improvements were noted in each group. Significant improvements in anatomical measurements both at mid- and long-term follow-ups suggest a durability of transvaginal mesh augmentation in prolapse surgery, especially in this high risk prolapse population with 46% having at least one previous prolapse surgery (hysterectomy not included) in the current study.

Mesh exposure is a unique and the most common procedure-related complication following synthetic graft augmentation. Our long-term exposure rate (6%) was slightly higher than previously observed (2%) in our mid-term follow-up study.[9] These rates are compatible with the lower end of existing data, from 1–24%; most falling under 15%. [9,14,20,22–29] As expected, all exposures in this study were seen in patients with significant vaginal atrophy noted on examination. All had discontinued vaginal estrogen use after surgery. Other proposed risk factors for mesh exposure include concurrent hysterectomy, inverted T colpotomy, and women with diabetes having a 7-fold increased risk.[30,31]

The impact of transvaginal mesh surgery on sexual function is somewhat conflicting in the current literature.[13,29,32,33] Our data suggest that mesh surgery does not negatively impact sexual function at long-term follow-up as assessed using the Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire. Dyspareunia was observed in 36% of the study population, which was higher than existing mesh data, 2–20%. [15,22,27,29,34,35] However, the actual de novo dyspareunia related to mesh augmentation is unclear as we did not explore the baseline rate of dyspareunia in this study population. In addition, dyspareunia is not unique to mesh augmentation. Following traditional native tissue prolapse surgery, nearly 19–37% reported dyspareunia.[27,36,37] Existing data suggest that dyspareunia is not associated with patient dissatisfaction after pelvic surgery. Even with the presence of dyspareunia, as high as 85% of patients were satisfied with their surgical results. [35–37]

In the current study, 84.3% of patients in long-term follow-up were somewhat or completely satisfied compared to 96% at mid-term follow-up. The goal of surgical treatment for pelvic organ prolapse is to restore anatomy, improve pelvic floor function and women's quality of life. Transvaginal mesh augmentation for pelvic organ prolapse was introduced as a more durable yet minimally invasive option to overcome the high recurrence rate of native tissue repair. Existing studies have reported the objective success rates ranging from 79 to 96% for transvaginal mesh augmentation versus 30 to 60% for traditional native tissue repair.[8,9,13–24] However, these studies need careful interpretation as various criteria were used to define “success”. When reanalyzing original data using a composite objective and subjective outcome measures, success rates of native tissue repair have been noted to be higher than previously reported.[38] Controversy in synthetic mesh use exists especially following the Food and Drug Administration (FDA) statements concerning the device-related complication rates.[39,40] The national gynecological and urological organizations currently advise discriminant use of synthetic mesh to augment vaginal defects in high-risk individuals, if the benefit may justify the risk of mesh surgery, and should be performed by trained surgeons with experience with complex pelvic reconstructive procedures after thorough counseling.[39–41] No definitive indications for synthetic mesh use have been

defined. However, current data suggest that mesh augmentation may be beneficial in women with a higher risk of developing recurrence, such as with advanced stage (stage III) prolapse, repetitive increased intra-abdominal pressure, deficient fascia especially in the anterior compartment, history of recurrence after native repair.[42] Advanced prolapse in younger women <60 years old has been reported having a greater risk for recurrent prolapse, however controversial.[4]

This study is limited by the retrospective design to identify eligible subjects. Women were recruited from a single institution. However, surgeon bias was avoided by having 5 attending surgeons participated in the study. Although retrospective, we also attempted to limit further bias by having the postoperative examination performed by a physician not primarily involved in the patient's surgical management. Another limitation is the relatively high attrition rate. This study was conducted at a major tertiary referral center for urogynecology in the Southeastern US. Thus, it is challenging to recruit participants greater than 5 years out of surgery due to the distance travelled for follow-up visits for many patients. However, the analysis comparing the characteristics of the study population to non-responders showed no significant differences, except for hypertension and the type of Prolift™ used. Interestingly, a higher proportion of subjects in the “non-responders” group had posterior or combined Prolift™ types. It is unclear whether the reason not to participate in the study is because of the negative impact of the surgery or possible complications related to either type of Prolift™. One of the unique challenges in pelvic floor surgeries using synthetic grafts in both counseling and performing subsequent follow-up studies is the bias created by the tremendous media attention regarding lawsuits targeting women who had previous mesh surgery. Due to the challenge in recruiting, we extended the current study by 18 months from the original mid-term study period (July 2006 – June 2007),[9] and meeting the minimum follow-up duration of 5 years (July 2006 – December 2008). Because of the study period expansion, not all subjects in the current study participated in the previous mid-term study. Thus, we were unable to perform a valid direct comparison of the outcomes between mid-term (1 year) and long-term (>5 years) follow-up.

Strengths of this study include the long-term follow-up duration assessing both objective and subjective outcomes. The mean follow-up of 7 years (ranges 5.8 to 8.1) is the longest duration reported in the current literature. This study reported functional outcomes using standardized validated questionnaires to assess symptom distress and the impact on QOL after transvaginal synthetic mesh surgery. We further explored the overall treatment success rate (70%), combining objective anatomic success, subjective success and the absence of retreatment (both surgical and conservative) as recommended by existing studies including the National Institution of Health, Pelvic Floor Disorders Network.[40]

Conclusion

In conclusion, although limited by the relatively low follow-up rate, this study provides the longest follow-up data assessing both subjective and objective outcomes in the current literature. Synthetic graft augmentation in transvaginal POP surgery can be a viable option with positive outcomes at long-term follow-up. It is important to individualize treatment based on the patient's medical and surgical history, the nature of the anatomical defect, and

her preference after thorough counselling regarding the risks, benefits, and alternatives to each treatment modality. Prospective randomized data is urgently needed to identify optimal candidates, location of insertion, and material type as well as safety and efficacy of synthetic graft use in transvaginal pelvic organ prolapse surgery.

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Table 1

Patient Demographics

	Long term follow-up (n=70)	Non-responders (n=138)	P-value
Age (years)	60.3 ± 9.3	61.8 ± 9.2	0.36
BMI (kg/m ²)	28.3 ± 5.4	29.1 ± 6.2	0.59
Parity	2.66 ± 1.14	2.5 ± 1.1	0.53
Race			0.21
White	68 (97.1)	107 (92.2)	
Other	2 (2.9)	9 (7.8)	
Prolift type			0.003
Anterior	33 (47.1)	27 (23.3)	
Posterior	23 (32.9)	50 (43.1)	
Combined	14 (20.0)	39 (33.6)	
Menopausal	65 (92.9)	110 (96.5)	0.30
HTN	30 (42.9)	69 (59.5)	0.03
DM	10 (14.3)	16 (13.8)	1.00
Asthma	9 (12.9)	11 (9.5)	0.47
Previous Hysterectomy	58 (82.9)	104 (90.4)	0.17
Previous Incontinence Surgery	23 (32.9)	29 (25.2)	0.31
Previous Anterior Repair	27 (38.6)	40 (35.1)	0.64
Previous Posterior Repair	12 (17.1)	26 (22.8)	0.45

Mean ± SD or Number (%)

Table 2

Objective and Subjective Outcomes

	Pre-operative	Post-operative	Change	P-value
POP-Q stage *				<0.001
Stage 1	1 (1.5)	22 (48)	-	
Stage 2	31 (44.9)	24 (52)	-	
Stage 3	31 (44.9)	0	-	
Stage 4	6 (8.7)	0	-	
Overall **	3 (1–4)	2 (1–2)		<0.001
Ba **	1	–2	–3	<0.001
Bp	0	–3	–3	<0.001
C	–3	–7	–4	<0.001
TVL	10	8	–2	<0.001
GH	4.5	3	–1.5	<0.001
PB	3	3.25	0.25	0.006
PFIQ ***	100.0±82.2	55.4±72.4	–44.6±9.8	<0.001
UIQ	34.3±27.9	21.7±26.4	–12.6±1.5	0.001
POPIQ	37.5±32.7	13.2±23.0	–24.3±9.7	<0.001
CRAIQ	26.2±32.2	21.3±28.6	–4.9±3.6	0.29
PFDI ***	141.6±57.6	87.1±67.0	–54.5±9.4	<0.001
UDI	47.7±24.4	34.1±28.4	–13.6±4.0	<0.001
POPDI	58.1±22.0	24.0±25.4	–34.1±3.5	<0.001
CRADI	36.0±26.8	29.9±23.4	–6.06±3.3	0.11
PISQ ***	27.5±9.4	30.1±9.2	2.6±0.2	0.14

*
N (%)**
median (range)***
mean ± SD

Table 3

Objective and Subjective Outcomes by different types of Prolift

	Anterior Prolift (n=33)				Posterior Prolift (n=23)				Combined Prolift (n=14)			
	Pre-op	Post-op	Change	P-value	Pre-op	Post-op	Change	P-value	Pre-op	Post-op	Change	P-value
POP-Q*												
Stage 1	0 (0.0)	11 (50.0)	-		1 (4.6)	6 (42.9)	-		0 (0.0)	5 (41.7)	-	
Stage 2	13 (39.4)	9 (40.9)	-		15 (68.2)	8 (57.1)	-		3 (21.4)	7 (58.3)	-	
Stage 3	17 (51.5)	0 (0.0)	-		5 (22.7)	0 (0.0)	-		9 (64.3)	0 (0.0)	-	
Stage 4	3 (9.1)	0 (0.0)	-		1 (4.6)	0 (0.0)	-		2 (14.3)	0 (0.0)	-	
Overall**	3.0 (1-4)	1.5 (1-4)		<0.001	2 (1-4)	2 (1-4)		0.03	3 (1-4)	2 (1-4)		0.002
Ba**	1.5	-2.5	-4.0	<0.001	-1.3	-2.0	-0.8	0.84	2.75	-1.5	-4.25	0.002
Bp	-2.0	-2.5	-0.5	0.13	0.0	-3.0	-3.0	<0.001	0	-2	-2	0.006
C	-3.0	-6.0	-3.0	<0.001	-6.0	-7.0	-1.0	0.08	-1	-8	-7	0.002
TVL	9.0	8.0	-1.0	0.09	10.0	8.0	-2.0	0.02	10.5	8	-2.5	0.02
GH	4.5	3.0	-1.5	0.006	4.0	3.0	-1.0	0.02	6	3.5	-2.5	0.02
POPIQ	31.5±34.0	8.2±15.5	-23.3±18.5	0.02	43.1±28.2	21.6±27.5	-21.5±0.7	0.007	42.4±37.4	11.2±27.1	-31.2±10.3	0.02
POPDI	60.6±21.8	22.3±22.2	-38.3±0.4	<0.001	52.9±25.4	28.8±28.8	-24.1±3.4	0.02	60.9±14.8	19.9±27.4	-41.0±12.6	0.002
PISQ***	29.8±6.3	29.6±9.6	-0.2±3.3	1.0	29.1±9.5	31.9±10.6	2.8±1.1	0.07	22.0±12.1	28.3±6.9	6.3±5.2	0.50

* N (%)

** median (range)

*** mean ± SD