Original article

Two year outcome data on efficacy and quality of life following mesh augmented vaginal reconstruction

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Abstract: Objective: To evaluate quality of life 2 years following mesh augmented vaginal reconstructive surgery. Methods: Patients who underwent a mesh augmented vaginal reconstructive surgery during an 18 month period were invited to participate. Subjects filled out validated quality of life questionnaires (PFDI, PFIQ and PISQ), underwent POP-Q examination and were asked if they would have the surgery over again and if they would recommend it to a friend. Results: Eighty-one patients underwent a mesh augmented repair; 38 (46.9%) consented to return for follow-up. The average length of follow-up was 25 +/- 6 months. The QOL measures showed improvement comparing pre-operative to post-operative scores (PFDI: 239.2 vs. 26.5; PFIQ: 152.2 vs. 4.8). Eighty-four percent said they would have the surgery again and 95% would recommend it to a friend. Conclusion: We found an overall improvement in patients' quality of life, subjective and objective outcome 2 year post-operative, following mesh augmented vaginal reconstruction.

Key Words: Mesh, Prolapse, Quality of Life, Vaginal reconstruction

INTRODUCTION

A woman has an 11% lifetime risk for pelvic organ prolapse and a third of patients who undergo corrective surgery have repeat procedures.[1] Methods of repair vary greatly and there is limited evidence to help guide surgeons to determine which techniques have better outcomes. The high rates of failure with traditional colporrhaphy[2] have led to the use of graft materials to augment pelvic floor reconstruction. This has led to the debate as to what graft material is best? To help answer this question one has to look at both objective outcomes as identified by the surgeon as well as patient perception regarding success of the surgery and improvement in their quality of life. Our study presented here evaluates the objective, subjective and quality of life outcomes for a single surgeon's use of synthetic mesh over an eighteen month period for the correction of pelvic organ prolapse.

MATERIALS AND METHODS

After institutional review board approval, a cohort of subjects who underwent polypropylene mesh augmented vaginal reconstruction between June 2005 and December 2006 were asked to participate in the study. Vaginal reconstructive surgeries included any prolapse repair of the anterior, posterior or apical compartment using mesh. Based on the practice patterns of the primary surgeon, this included the use of polypropylene mesh in one of two ways. The graft was positioned in the appropriate compartment(s) in the vagina and secured utilizing suture or tension free mesh arms brought through the obturator foramen or ischiorectal fossa to achieve surgical correction of the prolapse. Our "traditional" anterior repairs included the use of a 10 X 15 cm polypropylene mesh (Polyform, Boston Scientific Corp., Boston MA or Pelvitex, Bard Corp., Atlanta, GA) cut in a trapezoidal fashion, anchored to the arcus tendineus fascia pelvis from the level of the ischial spines to the bladder neck. The alternative technique for anterior repair utilizes a prefabricated piece of polypropylene mesh with arms as described above using what is commonly referred to as a "lift kit" (Avaulta Anterior, Bard Corp., Atlanta, GA). Our "traditional" posterior repairs included the use of a 10 X 15 cm polypropylene mesh (Polyform, Boston Scientific Corp., Boston MA or Pelvitex, Bard Corp., Atlanta, GA) cut in a "top hat" like fashion with the 15 cm side of the mesh anchored to the sacrospinous ligaments bilaterally and the distal portion of the mesh anchored to the levator fascia laterally and the rectovaginal septum distally. The alternative technique for posterior repair utilizes a posterior "lift kit" placed in the ischiorectal fossa as previous described (Avaulta Posterior, Bard Corp., Atlanta, GA).

Each patient underwent a pelvic exam with prolapse staging utilizing the Pelvic Organ Prolapse Quantification scale (POP-Q) [3] pre-operatively, at 3 months and an average of 25 +/- 6 months post-operatively. At the initial pre-operative and 2 year post-operative visits, patients filled out validated questionnaires. Pre-operative and post-operative questionnaires included the long and short form versions, respectively of the Pelvic Floor Distress Inventory (PFDI) and the Pelvic Floor Impact Questionnaire (PFIQ).[4] Both of these questionnaires contain 3 domains assessing prolapse, colorectal and urinary dysfunction. At the 2 year follow-up visit patients additionally filled out the Prolapse and Incontinence Sexual Function Questionnaire short form (PISQ-12).[5] Subjective evaluation was based on three questions asked to the patients at an average of 25+/- 6 months post-op: 1) Would you do the surgery all over again? 2) Would you recommend the surgery to a friend? 3) In terms of your prolapse how do you feel; 1: markedly worse, 2: worse, 3: same, 4: improved, 5: markedly improved? Patients who did not return for participation in the study, were contacted by telephone and were specifically asked questions 1 and 2. These two questions were chosen because of their ability to have a concise yes or no answer.

A retrospective chart review was performed to collect the following data for analysis: patient demographics, POP-Q results, PFDI and PFIQ scores, post-operative physical examination findings, additional surgical interventions and length of follow-up. Independent T test, Fisher Exact test and Pearson Chi Square test were used to determine if there was any demographic data associated with surgical failure. Mean, median and standard deviations were calculated for objective and subjective data.

RESULTS

Eighty-one patients, during the study period had a mesh augmented vaginal repair. Demographic data for all patients are listed in Table 1. Thirty-eight patients (46.9%) consented to return for this study and were included in the analysis. Of these 38 patients, the mean age at the time of surgery was

Table 1 – Demographics for all 81 Patients

Age (yrs) (Mean (St Dev) / Range)	58 (10)	38-84
BMI kg/m^2 (Mean (St Dev) / Range)	29.1 (5.5)	19.7-50.1
Parity (Mean (St Dev) / Range)	3.3 (1.8)	0-10
Tobacco users (N / %)	18	22
Premenopausal (N / %)	17	21
Postmenopausal (N / %)	64	79
HRT (N / %)	8	10
Vaginal estrogen only	3	4
Oral estrogen only	2	2.5
Estrogen patch	1	1.2
Vaginal and oral estrogen	2	2.5
Race (N / %)		
Not recorded in chart	30	37
White	40	49
African American	3	4
Hispanic	8	10
Diabetes Mellitus	9	11
Previous Hysterectomy	24	30
Previous prolapse or incontinence procedure	13	16
Urodynamics (UDTs)		
No UDTs pre-op	14	17
UDTs pre-op	67	83
Detrusor Overactivity Pre-op	15	18.5
Pre-op Stress Incontinence by UDT	37	46

BMI – Body mass index; HRT – Hormone replacement therapy

59 +/- 9.9 years. Most patients were Caucasian (84%), post-menopausal (84%), and did not have a hysterectomy prior to the vaginal reconstructive procedure (68%). The average length of follow-up was 25 +/- 6 months. Five patients had an anterior polypropylene mesh augmented repair only: 4 were performed using the Avaulta Anterior lift kit and 1 was performed using a Polyform mesh suture based repair. Seven patients underwent a posterior polypropylene mesh augmented repair only: 4 were performed using the Avaulta Posterior lift kit and three using a Polyform mesh suture based repair. Twenty-six patients had a combined anterior and posterior polypropylene mesh augmented repair: seventeen patients had a combined graft augmented suture based repair: 13 were performed with Polyform and 4 were with Pelvitex. Of the remaining 9 patients, Avaulta Anterior and Posterior lift kit was placed in 8 patients and 1 patient had an anterior repair with Polyform and a site-specific posterior repair.

The mean and median pre-operative, three month post-operative and two year post-operative POP-Q points of the thirty-eight patients seen for follow up are found in Table 2. Of the 3 patients with stage 3 prolapse, 2 had undergone a posterior repair only and presented with a stage 3 anterior prolapse at their latest follow-up visit. For the purposes of our analysis these 2 patients were counted as having recurrent prolapse although the initial defect repair was in a different compartment. Two of these three patients with stage 3 prolapse said they would have the same surgery again and the other patient said she was unsure.

All of the eleven patients who had stage 2 recurrent prolapse were found to have the defect in the anterior compartment. One patient had stage 2 prolapse in both anterior and posterior compartments. Another patient initially underwent a posterior repair and was found to have stage 2 anterior prolapse at her two year follow-up visit. She was also added as another patient with recurrent prolapse. In response to our subjective quality of life measures nine of these subjects said they would have the surgery again, one said she would not have the surgery again and one said she was unsure. All fourteen of the patients considered to have recurrent prolapse (defined as greater than or equal to stage 2 at their 2 year follow-up visit) said they would recommend the surgery to a friend. In all subjects with stage 2 prolapse at follow-up the greatest point of descent on the POP-Q was an Aa of -1. There was a trend suggesting that those who had recurrent prolapse or were our surgical failures were more likely to have had previous urogynecologic procedures. (p=0.052) There were no other associations with surgical "failure" (Table 3). The information in table 3 is not stable due to the small sample size.

Of the forty-three patients who did not participate in the study, twenty-one were able to be reached by phone. Twenty stated they would have the surgery again and would recommend it to a friend. Table 4 demonstrates the mean and median scores from the quality of life surveys of the patients who followed-up 2 years post-op. Twenty-seven out of thirty-eight patients filled out the long form version of the PFDI and PFIQ pre-operatively and thirty-five of thirty-eight patients filled out the short version of these questionnaires post-operatively. The median pre-operative PFDI and PFIQ was 256.7 and 143.9 (long form) respectively and post-operatively 29.1 and 4.8 (short form) respectively. This demonstrates an overall improvement in quality of life symptoms. The PISQ-12 was filled out by twenty-four patients post-operatively with results seen in Table 4. Twelve were not sexually active at the time of follow-up and two did not complete the survey. We did not have pre-operative PISQ-12 scores.

There were two subjects who underwent additional surgery for recurrent prolapse during the two year follow-up period. There was one mesh erosion found in the thirty eight patients (2.6%) who followed up at two years. Eighty four percent of these patients said they would have the surgery again and 95% would recommend the surgery to a friend. The median score for satisfaction was 5: markedly improved.

Table 2 – POP-Q points for pre-operative, 3 month post-operative and 2 year follow-up visit (for patients who had long term follow-up (N=38).

POP Q Points	**Pre-op Mean(std dev)/Median**		**3 mos Post-op Mean(std dev)/ Median**		**2 year Follow-up Mean (std dev)/ Median**	
Aa	0.89(1.89)	1	-2.72(0.61)	-3	-1.92(1.24)	-2
Ba	1.39(2.36)	1.5	-2.66(0.75)	-3	-1.47(1.18)	-2
Ap	-1.53(1.47)	-2	-2.95(0.23)	-3	-2.89(0.31)	-3
Bp	-1.45(1.52)	-2	-2.95(0.22)	-3	-2.82(0.46)	-3
C	-3.04(4.17)	-4.75	-7.08(3.20)	-7.5	-6.30(1.39)	-6
D	-6.33(1.74)	-6.5	-9.40(1.14)	-9	-7.00(1.00)	-7
TVL	9.79(0.84)	9.75	9.21(1.02)	9	8.22(1.18)	8
GH	4.42(1.19)	4.25	2.78(0.63)	3	3.20(0.72)	3
PB	3.73(1.18)	3.5	4.46(0.74)	4.75	4.14(0.79)	4

Table 3 – Associations with Surgical Failure

	Stage of Prolapse at 2 Year Visit *		P-Value
	0 or 1 (N=24)	≥2 (N=14)	
Race			
Caucasian (N/%)	21 (87.5)	11 (78.6)	
African American (N/%)	0 (0.0)	2 (14.3)	
Hispanic (N/%)	3 (12.5)	1 (7.1)	0.153
Age (yrs) (Mean)	57.33	62.57	0.114
BMI (kg/m^2) (Mean)	27.94	29.71	0.325
BMI			
Obese (BMI ≥30) (N/%)	7 (29.2)	7 ((50.0)	
Not Obese (BMI<30)	17 (70.8)	7 (50.0)	0.199
Tobacco Users			
Yes (N/%)	5 (20.8)	1 (7.1)	
No (N/%)	19 (79.2)	13 (92.9)	0.383
Postmenopausal			
Yes (N/%)	20 (83.3)	12 (85.7)	
No (N/%)	4 (16.7)	2 (14.3)	1.000
Hormone Replacement Use			
Yes (N/%)	2 (8.3)	3 (21.4)	
No (N/%)	22 (91.7)	11 (78.6)	0.337
Diabetes Mellitus			
Yes (N/%)	1 (4.2)	3 (21.4)	
No (N/%)	23 (95.8)	11 (78.6)	0.132
Previous Hysterectomy			
Yes (N/%)	8 (33.3)	4 (28.6)	
No (N/%)	16 (66.7)	10 (71.4)	1.000
Previous prolapse or incontinence procedure			
Yes (N/%)	3 (12.5)	6 (42.9)	
No (N/%)	21 (87.5)	8 (57.1)	0.052
EBL (Mean)	315.22 ml	371.43 ml	0.476
EBL >500 ml			
Yes (N/%)	4 (17.4)	3 (21.4)	
No (N/%)	19 (82.6)	11 (78.6)	1.000

* Stage 2 or greater considered recurrent prolapse or surgical failure
BMI – Body Mass Index
EBL – Estimated Blood Loss at time of reconstruction

Table 4 – Results of Questionnaires Pre-operatively and at 2 year Follow-up visit for the Patients who had long term follow-up

PFDI		Pre-op N=27 (Long Forms)		2 yr follow N=35 (Short Forms)	
	POPDI-6 Mean (std dev)/Median	103.8(57.2)	1Œ07.7	14.0(21.0)	8.3
	CRADI-8 Mean (std dev)/Median	72.0(67.8)	60.1	14.8(18.2)	7.85
	UDI-6 Mean (std dev)/Median	89.5(65.2)	72.2	18.9(21.0)	8.3
	Total Mean (std dev)/ Median	265.3(159.7)	256.7	48.5(50.8)	29.1
PFIQ	UIQ-7 Mean (std dev)/Median	108.4(91.5)	98.35	7.9(12.8)	0
	CRAIQ-7 Mean (std dev)/Median	57.3(81.3)	21	9.2(23.3)	0
	POPIQ-7 Mean (std dev)/Median	57.0(81.8)	20.4	3.9(9.8)	0
	Total Mean (std dev)/ Median	222.6(214.7)	143.9	21.3(37.6)	4.8
PISQ 12 N=24*		Not Done	Not Done	88.1(19.6)	92.9

*12 patients were not sexually active at time of 2 year f/up and 3 did not complete any surveysŒ

DISCUSSION

In surgery for pelvic organ prolapse, there is increasing evidence in support of the use of mesh when correcting pelvic floor defects.[66-11] This management is supported by a recent Cochrane Review reporting a higher risk of recurrent prolapse after anterior colporrhaphy than after mesh repairs.[72] The availability of "lift kits" has resulted in more surgeons performing mesh augmented repairs for pelvic organ prolapse. This study demonstrates an overall improvement in the quality of life and outcome variables two years post-operative following mesh augmented vaginal reconstruction in a busy urogynecology practice. Many complications can occur from the use of mesh in the vagina. These complications include sexual dysfunction, de novo stress urinary incontinence or fecal incontinence, voiding dysfunction, pain, failure, and reoperation risk. [12-17] Any of these complications can affect a person's quality of life. A recent warning by the Food and Drug Administration describes many of these risks (http://www.fda.gov/cdrh/safety/102008-surgicalmesh.html). Subjective and objective data in this study demonstrate an overall improvement in quality of life following these procedures and the majority of patients would do their procedure again with the knowledge of their experience since the surgery. These results infer that these risks are likely minimal. Previous studies have defined failure as a POP-Q staging of 2 or greater. Stage 2 prolapse is defined as any point between -1 and +1, relative to the hymenal ring. In our study, all patients with Stage 2 prolapse at follow-up had no point of descent greater than -1. Most of these patients were unaware of any recurrence and were pleased with the results of their surgery based on the subjective questions put forth to them. This might lead us to redefine failure from a subjective point as opposed to a purely objective one. Of the three patients with stage 3 recurrent prolapse, two of them had a failure in the compartment not operated on at the time of their initial surgery. It is often a struggle in the field of urogynecology to decide whether to prophylactically repair an otherwise asymptomatic defect. Although these numbers are small, this might lead us to consider repairing even minor defects in compartments opposite to those which appear to be causing the patients complaints. More evidence is needed in this area. Some of the limitations of this study include the retrospective nature of our data as well as the limited percentage of patients who followed up at two years. Although our rate of return was comparable and acceptable compared to other studies we would have liked to have seen a greater long term follow up rate. Other limitations include the varying brands of mesh as well as different techniques employed to perform these repairs. Our practice now uses the short form versions of the PFDI and PFIQ and thus made it difficult to show an exact comparison of data secondary to the use of the long form versions used previously. Unfortunately, at the time of this study, the PISQ-12 surveys were not filled out by our patients pre-operatively. It is now our practice to include this survey in our pre-operative packet distributed to all patients at their initial office visit. We can not make any assumptions with regards to patients' change in sexual function following graft

augmented repairs. However, we can say that other similar studies have demonstrated similar results for the overall PISQ-12 score as our study. [18, 19] The strength of our study is its long term follow-up after the use of polypropylene mesh for a single surgeon in vaginal reconstruction. Subjective questions and objective validated questionnaires along with other outcome variables demonstrate overall satisfaction and efficacy.

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