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Outcomes of vaginal reconstructive surgery with and without graft material

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KEY WORDS

Pelvic organ prolapse
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Graft
Complications
Surgical outcome

Objective: This study was undertaken to evaluate the outcomes of vaginal surgery for pelvic organ prolapse, comparing cases implementing graft augmentation to those without graft augmentation.

Study design: This was a retrospective cohort study of 312 patients who underwent vaginal surgery for prolapse from February 1998 to January 2004.

Results: Of the 312 patients, 98 (31.4%) had graft augmentation. The median follow-up was 9 months (3–67 months). Graft use was not associated with reduction in recurrent prolapse, recurrent stage 3 prolapse, recurrent incontinence, or additional surgery for prolapse. After controlling for confounders, there was still no difference in surgical outcomes. Complications such as vaginal/graft infection (18.4% vs 4.7%; $P < .001$) and granulation tissue (38.8% vs 17.3%; $P < .001$) were more common after cases in which graft was used.

Conclusion: In the early postoperative period, there was no benefit in using graft for prolapse repair. Graft use leads to a higher rate of postoperative complications.

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Pelvic organ prolapse (POP) is a very common condition that will affect as many as 50% of women in the United States.¹ Approximately 11% of women will undergo surgery for POP at least once in their lifetimes.²

When a patient elects to have surgery for POP, the route of surgery is often at the discretion of the operating surgeon. Advocates of abdominal surgery, who normally perform abdominal sacrocolpopexy (ASC) using mesh, contend that their repair is more durable

because it is a compensatory surgery. A compensatory surgery is one that does not rely on the patient's own tissue (ie, using graft to bolster the repair).³ Although there is some support for this contention,⁴ the topic remains controversial.

With few comparative trials assessing surgical outcomes, recommendations on surgical route are often based on preference. Advocates of vaginal surgery tout the advantages of diminished pain and quicker recovery.⁵ Patients may prefer vaginal surgery for cosmetics. Consequently, most surgical modifications for correction of prolapse have focused on vaginal procedures.

A rapidly evolving technique involves augmentation of vaginal repair by using graft material. There are many

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different materials available, including both synthetic and biologic. The graft can be used to augment repair in the anterior or posterior vaginal wall. Although techniques may vary, graft is generally attached bilaterally to the pelvic sidewall (eg, arcus tendineus), creating a hammock to reinforce the native support tissue. This technique is therefore a compensatory repair. Results have been favorable, with anatomic success rates ranging from 59% to 94%.⁶⁻⁸ Unfavorable consequences do occur with reports of worsening dyspareunia⁸ and a higher incidence of recurrence in other vaginal compartments.⁹ The lack of comparative data and anticipated higher incidence of graft-related complications (ie, graft erosion and infection) has led to some debate among vaginal surgeons about the necessity of graft use.

The purpose of this study is to see if graft augmentation improves surgical outcomes in vaginal surgery when compared with more traditional repair.

Materials and methods

Data were collected retrospectively from the office charts of patients having undergone surgery for POP from February 1997 to January 2004. The Institutional Review Board of the Louisiana State University Health Sciences Center granted approval for the study. Charts were systematically reviewed in all patients who underwent vaginal reconstructive surgery for prolapse during the indicated time interval by the 2 senior authors (R.R.C, N.F.).

Cases in which graft was used to support the anterior vaginal wall, posterior vaginal wall, or both defined the graft-augmented cases. These cases were compared with those in which restorative repairs (ie, no graft) were performed during the same interval. The choice of procedure (compensatory or restorative) as well as of graft material had been at the discretion of the primary surgeon. Patients were excluded if the procedure was obliterative (ie, colpocleisis). Cases were excluded from analysis if the operative report was not available. Only patients with at least 3 months of follow-up were included in the study.

The technique for anterior vaginal wall fixation involved fashioning a trapezoid shape from the graft to cover the entire vaginal wall. After opening the entire anterior vaginal wall through a midline incision, the graft was fixed bilaterally to the arcus tendineus fascia pelvis by using at least 3 permanent sutures on each side. The graft was fixed apically either to the vaginal apex or bilaterally to the uterosacral or sacrospinous ligaments if a concurrent vault suspension was performed. The technique was similar for posterior grafts, with lateral fixation to the arcus tendineus fascia rectovaginalis.

Data collected included demographic and background data, such as previous surgical history. The

initial visit, operative report, and all postoperative visits were reviewed. Staging was by the Baden-Walker Halfway (BWH) system¹⁰ in most patients and the Pelvic Organ Prolapse-Quantification (POP-Q)¹¹ system in some during this interval. Because it is easier to convert the POP-Q to the BWH and not vice versa, for the purpose of this article, all staging will be described according to the BWH system.

Patients were evaluated at each postoperative visit for recurrent pelvic floor disorders. Recurrent prolapse, defined as any descent of any compartment of the vagina below the normal anatomic position (greater than stage zero by the BWH system), was the primary outcome variable. Recurrent stage 3 prolapse was defined as any prolapse beyond the hymen. Recurrent incontinence was defined as any subjective incontinence recorded in the chart during the postoperative visits. Patients requiring additional surgery for POP or incontinence were identified only if the additional surgery was performed by 1 of the 2 primary surgeons.

Secondary outcome variables included graft-related complications such as granulation tissue, vaginal infection, and the need for surgical treatment of these complications. Follow-up interval was defined as the time interval (months) from surgery to the last postoperative visit. In the case of those patients who had additional surgery, the follow-up interval was defined as the time from initial surgery to the second surgery.

Statistics usage

Data were recorded in a paper database before compilation into a computer database (Microsoft Access, Microsoft Corp, Redmond, WA). Statistical analysis was performed with the use of Statistical Package for Social Sciences 11.0 for Windows (SPSS Inc, Chicago, IL). Student *t* test was used to compare means for continuous variables. The χ^2 test was used to compare categorical data. Fisher exact test was performed when the assumptions for the χ^2 distribution were violated. The Mann-Whitney *U* test was used to compare means when normality assumptions were violated. Logistic regression was used to create both univariate and multivariate models. A *P* value less than .05 was considered significant.

Results

Of 502 patients undergoing surgery during this time frame, 441 had at least 1 postoperative visit. Another 34 patients who had abdominal surgery were also excluded from analysis. After excluding another 95 patients who had less than 3 months of follow-up, 312 patients were available for analysis. Demographic data for the cohort are described in Table I. Women in whom graft was used were older (and consequently menopausal), more parous, and more likely to have had posterior repairs

Table I Demographic data for the cohort

Category	Graft (n = 98)	No Graft (n = 214)	Significance
Age (y)	65.4	60.7	.003
Body mass index (kg/m ²)	26.3	26.1	.892
Gravidity	3.6	3.4	.224
Parity	3.3	2.9	.018
POP-Q measurements (cm) (n = 60)*			
Aa	1.0	0.6	.508 [†]
Ba	3.2	2.7	.709 [†]
C	1.6	0.2	.828 [†]
GH	6.0	5.2	.265 [†]
PB	3.3	3.9	.639 [†]
TVL	7.5	8.3	.213 [†]
Ap	-0.4	-0.6	.403 [†]
Bp	1.2	0.7	.434 [†]
Race (%)			.456
White	72 (73.5%)	147 (68.7%)	
Black	5 (5.1%)	6 (2.8%)	
Hispanic	3 (3.1%)	7 (3.3%)	
Unknown	18 (18.4%)	54 (25.2%)	
Previous hysterectomy	82 (83.7%)	163 (76.9%)	.172
Prior reconstructive surgery	48 (49.0%)	80 (37.6%)	.057
Tobacco use (n = 305)			.728
If yes, packs per day	1.0	1.0	.855
Menopausal (n = 304)	89 (92.7%)	173 (83.2%)	.025
If menopausal, % on HRT (n = 258)	61 (70.1%)	131 (76.6%)	.258
Concurrent anti-incontinence surgery	66 (67.3%)	142 (66.4%)	.863
Procedures			
Hysterectomy	7 (7.1%)	23 (10.7%)	.316
Uterosacral ligament suspension	45 (45.9%)	106 (49.5%)	.553
Sacrospinous ligament suspension	17 (17.3%)	18 (8.4%)	.020
Posterior repair	37 (37.8%)	31 (14.5%)	< .001
Perineorrhaphy	28 (28.6%)	30 (14.0%)	.002
Follow-up interval (mo)	11.6	15.0	.027

Means were compared by using independent sample *t* test, except where noted. Categorical data were compared with the use of χ^2 test. HRT, Hormone replacement therapy.

* Point D was not included in analysis because it was measured in only 1 case with graft use.

[†] Mann-Whitney *U* test.

Table II Reconstructive procedures performed

Procedure	Number performed (%)
Vaginal hysterectomy	30 (9.6%)
Uterosacral ligament suspension	151 (48.2%)
Sacrospinous ligament suspension (bilateral)	35 (11.2%)
Vaginal paravaginal repair	123 (39.3%)
Graft-augmented anterior repair (hammock)	76 (24.2%)
Graft-augmented posterior repair (hammock)	24 (7.6%)
Posterior repair (site-specific)	68 (21.7%)
Perineorrhaphy	58 (18.5%)
Sphincteroplasty	8 (2.6%)
Other	8 (2.6%)
Anti-incontinence surgery	
Pubovaginal sling—bone anchor	169 (54.0%)
Pubovaginal sling—traditional or Cooper's ligament sling	19 (6.1%)
Midurethral sling	19 (6.1%)
Retropubic urethropexy	1 (0.3%)
Needle suspension	1 (0.3%)

and perineorrhaphies performed, while also having longer follow-up.

There were 98 patients who had 100 graft-augmented procedures as part of the vaginal repair. One surgeon (N.F.) performed the majority (n = 88) of the graft-augmented cases. All the procedures performed in this cohort are listed in [Table II](#). The numerous different biomaterials used for graft augmentation are listed in [Table III](#). Comparison of the numerous different graft materials used during this interval revealed no significant differences in any outcome or other variable. Analysis was limited because of the relatively small numbers in each group.

Comparison of recurrence rates based on location of graft use is provided in [Table IV](#). There was a trend toward a decreased incidence of recurrent prolapse (18.2% vs 40.5%; *P* = .054) when a posterior graft was used, mainly because of a decrease in recurrent posterior vaginal prolapse (4.5% vs 23.0%; *P* = .064). Subanalysis comparing biologic (n = 92) with synthetic (n = 6) graft revealed no difference in surgical outcomes or complication rates.

Because there was no difference between graft materials used, all cases in which graft was used for prolapse repair were grouped together and compared with those undergoing restorative repair. The results are shown in [Table V](#). There was no difference in any of the primary outcome measures assessing surgical outcome, even after controlling for confounders such as age, parity, follow-up interval, and surgical procedures. However, graft use was associated with more complications such as tissue granulation (38.8% vs 17.3%; *P* < .001) and

Table III Different graft materials used and site of use

Graft material	Anterior	Posterior	Both	Total
Freeze-dried cadaveric fascia lata (banked)	27	7	0	34
Solvent-dried cadaveric fascia lata (Tutoplast, Mentor, Santa Barbara, CA)	13	2	0	15
(Intaxen, American Medical Systems, Inc, Minnetonka, MN)	10	5	1	16
Porcine small subintestinal submucosa (SIS, Cook Biotechnology Inc, West Lafayette, IN)	10	1	0	11
Acellular porcine dermis (Pelvicol, Bard, Covington, GA)	7	3	0	10
Autologous fascia lata	4	1	1	6
Polypropylene (Gynemesh, Gynecare Worldwide, New Brunswick, NJ)	3	3	0	6
Total	74	22	2	98

Table IV Location of recurrence that is based on the location of graft placement

Location of recurrence	Location of Graft Placement		Significance
	Anterior graft* (n = 74)	Posterior graft (n = 22)	
None	44 (59.5%)	18 (81.8%)	.054 [†]
Anterior	14 (18.9%)	3 (13.6%)	.754
Posterior	17 (23.0%)	1 (4.5%)	.064
Apex	1 (1.4%)	0	> .99

Comparisons are made using the Fisher exact test, except where noted. Because there were only 2 cases involving multiple grafts, these were excluded from analysis.

* In 2 cases involving anterior vaginal grafts, the recurrence occurred with both the anterior and the posterior vaginal wall. In these cases, the recurrence is listed in both the anterior and posterior recurrence category. Therefore, the sum for the column equals 76.

[†] χ^2 test.

vaginal infection (18.4% vs 4.7%; $P < .001$), requiring more intervention and more office visits. These complications were most commonly managed by cautery, suture removal, and operative surgical intervention. In the cases in which graft was used, there were 25 (28.4%) cases of graft erosion, with 18 (72%) requiring debridement. The remaining 7 erosions were treated successfully with topical estrogen alone.

A regression model was created to define independent risk factors for granulation tissue and infection postoperatively. Initially, univariate analysis was performed to identify individual risk factors for postoperative

Table V Graft vs no graft in vaginal reconstructive surgery

Category	Graft (n = 98)	No graft (n = 214)	Significance
Recurrent prolapse	34 (34.7%)	91 (42.5%)	.190
Recurrent stage 3 prolapse	2 (2.0%)	6 (2.8%)	> .99*
Recurrent urinary incontinence	25 (25.5%)	59 (27.6%)	.703
Further surgery for prolapse	8 (8.2%)	20 (9.3%)	.734
Further surgery for prolapse or incontinence	13 (13.3%)	29 (13.6%)	.945
Postoperative complications			
Granulation	38 (38.8%)	37 (17.3%)	< .001
Infection	18 (18.4%)	10 (4.7%)	< .001
Management of complications (n = 75)			
Was patient symptomatic	30 (81.1%)	21 (56.8%)	.024
Cautery used	24 (63.2%)	9 (23.7%)	.001
Cut suture	12 (31.6%)	11 (28.9%)	.803
Surgery (in operating room)	8 (21.6%)	4 (10.5%)	.190
Interval from surgery (mo)	2.8	8.3	.003
Interval to resolution (mo)	4.7	3.0	.180
Number of office visits	3.6	2.8	.037

Means were compared using independent sample *t* test. Categorical data was compared by using χ^2 , except where noted.

* Fisher exact test.

complications. Having identified those outcomes, a logistic regression model was built incorporating all variables identified as significant on univariate analysis. With the use of a stepwise, backward technique, insignificant variables were sequentially removed until all variables were found to be significant. Outcomes of univariate and multivariate analysis are described in **Table VI**. Graft use (odds ratio [OR] 3.397 [1.878-6.145]) and use of braided suture (OR 2.853 [1.488-5.469]) were most associated with granulation, whereas women older than 70 years (OR 0.412 [0.206-0.787]) tended to be less likely to have granulation tissue ($r = 0.404$). Infection was associated with graft use (5.871 [2.058-16.745]), performance of a sacrospinous ligament fixation (OR 3.853 [1.220-12.175]), and black race (OR 14.907 [3.470-64.040]) ($r = 0.519$).

Comment

Improving surgical outcomes is the driving force for the many newer procedures being developed for reconstructive surgery. Because patients recover more quickly and

Table VI Univariate and multivariate analysis that used granulation as primary endpoint (only variables found significant on univariate analysis are listed in this table)

Variable	Granulation		Infection	
	OR	95% CI	OR	95% CI
Univariate				
Graft use	3.029	1.767-5.194	4.590	2.031-10.371
Braided suture	2.704	1.477-4.950	3.086	1.133-8.402
Age > 70 y	0.507	0.273-0.939	NS	
Black race	NS		10.440	2.887-37.756
Sacrospinous	NS		3.059	1.195-7.832
Multivariate				
	$r = 0.404$		$r = 0.519$	
Graft use	3.397	1.878-6.145	5.871	2.058-16.745
Braided suture	2.853	1.488-5.469	NS	
Age > 70 y	0.402	0.206-0.787	NS	
Sacrospinous	NS		3.853	1.220-12.175
Black race	NS		14.907	3.470-64.040

have fewer complications with vaginal surgery,⁵ most of these innovations in technique have focused on the vaginal route.

When Benson et al⁴ found that ASC was superior to vaginal sacrospinous ligament fixation (SSLF), reconstructive surgeons began to favor abdominal repair of the vaginal vault. Many proponents of abdominal surgery argue that compensatory repairs such as the ASC are more durable. Consequently, advances in surgical technique have focused on achieving the results of abdominal compensatory repair while still using the vaginal route favored by many.

With the resurgence of the site-specific defect repair in POP,¹² surgical procedure choice has evolved toward defect-directed repairs, such as the paravaginal repair and site-specific posterior repair. Unfortunately, the few comparative studies have showed little benefit of these “newer” procedures,¹³ leading to a continued search for a superior procedure.

Developed as a compensatory procedure, graft-augmented vaginal repair is 1 of the most recent innovations in surgical technique. Proponents of graft use in vaginal surgery have justified its use by extrapolating from hernia data that describe a more durable repair with less postoperative discomfort.¹⁴ Critics of graft use argue that the pathophysiology of prolapse and of abdominal hernias differs. Despite the controversy, an overabundance of biomaterials has become available for use in vaginal repair.

Many studies have described favorable results of graft augmentation. In the only trial comparing graft with no graft, Julian⁷ described the results of using polypropylene mesh in the anterior vaginal wall of 24 patients with recurrent prolapse. After nonrandomized allocation of 12 patients to site-specific repair and 12 patients to the same procedure with graft augmentation, the author concluded that graft use was more effective in

preventing recurrent prolapse (0% vs 33%; $P < .05$). There were 3 graft complications (25%) easily managed on an outpatient basis.

In a review of anterior vaginal graft using autologous fascia lata, Chesson et al¹⁵ found a recurrence rate of 31.3% for which only 1 patient (3.1%) required surgery. The graft complication rate was 18.8%. In a similar series fascia lata, Kobashi et al¹⁶ found a recurrence rate of 23.2% with a graft complication rate of 15.2%. Many other series have reported a wide range of success rates (59%-100%) with graft-augmented anterior repair.^{6,8,9,17-21}

The results with graft augmentation of the posterior vaginal wall have been slightly better in the few published case series. Miklos et al²² reported a 95% success rate in 57 patients using a dermal matrix. Milani et al⁸ found a high (94%) success rate for prolapse in 31 patients undergoing polypropylene mesh-augmented posterior repair. Unfortunately, there was a high rate of dyspareunia (69% compared with 6% preoperatively; $P < .05$) and vaginal erosion (6.5%). Using only functional outcomes, Mercer-Jones et al²³ demonstrated improvement in symptoms of straining and incomplete evacuation, although 27.2% still complained of a vaginal bulge. No objective assessment was described.

Unfortunately, the paucity of comparative data analyzing graft use has been disappointing. It is also difficult to compare the results of the various case series for many reasons. Differences in surgical technique, graft material, patient selection, and performance of concomitant procedures influences any comparison of results. Outcome measures vary between series with a lack of functional measures.

The comparative data presented here contradict the theory that graft use results in better outcomes. With regard to our main surgical outcome variables, in the early postoperative period there was no improvement when

graft was used. In addition, this study confirms the increased risk of complications such as erosion, infection, and granulation⁸ associated with graft use. Although the majority of these complications are relatively minor, they did result in more office visits and intervention.

There are several weaknesses to this study. First, the retrospective design limits the conclusions that can be drawn. The POP-Q would be a more ideal staging system. Controlling for surgeons performing the procedures would eliminate that potential source of bias. For logistical reasons, this was not done. The outcome variables were subject to recall and recording biases. Functional outcome variables were not assessed. The short follow-up interval only allows assessment of short-term outcomes.

One of the largest problems with this study involved patient selection. There was no protocol used to determine who would receive graft. In this retrospective study, we were unable to determine the reasons that some patients received graft and others did not, because the reasons were not recorded in the chart. This creates an obvious source of bias. Although we attempted to control for some risk factors for recurrent prolapse (ie, previous surgery, previous hysterectomy) in the logistic regression, this does not equate to the surgeon's preference and thought process. Ideally, the graft group should be randomized or matched to a control group for possible confounding variables. Although regression was used to control for objective variables, it is difficult to control for subjective variables (ie, surgeon's preference) that are impossible to measure.

Lumping all different graft materials together into 1 cohort is not ideal because all the varying materials used have different biomechanical properties. All grafts have different elasticity, durability, porosity, and tensile strengths. The origin of biologic grafts (ie, allograft, autograft, xenograft) certainly can influence outcomes. Biologic grafts can be acellular, cross-linked, and perforated. All these characteristics could certainly affect outcomes. No difference existed among the different materials leading to the decision to combine the cases. Although individual comparisons of graft would have been better, the smaller numbers in each group would have rendered such analysis fairly meaningless.

The ideal study would eliminate selection bias by randomizing patients for all surgeons. A single surgical technique using a sole biomaterial would be performed. The POP-Q and validated questionnaires would better measure outcomes. Longer follow-up is necessary. It is important that these studies be performed soon because biomaterial technology is progressing at an alarming rate. Using a well-designed protocol, the techniques should be thoroughly evaluated before mass marketing the products.

Additional avenues for study would include identifying and studying those patients who may be at higher

risk for surgical failure. Many surgeons have reserved graft use for patients whom they thought were at higher risk for failure. Further investigation would help support this theory.

In the early postoperative period, graft-augmented vaginal surgery appears to confer no added benefit over more traditional vaginal procedures for POP. The high rate of complications, although mild and easily treated, calls the routine use of graft into question.

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