Graft Use in Transvaginal Pelvic Organ Prolapse Repair

A Systematic Review

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OBJECTIVE: To estimate the anatomic and symptomatic efficacy of graft use in transvaginal prolapse repair and to estimate the rates and describe the spectrum of adverse events associated with graft use.

DATA SOURCES: Eligible studies, published between 1950 and November 27, 2007, were retrieved through Medline and bibliography searches.

METHODS OF STUDY SELECTION: To assess anatomic and symptomatic efficacy of graft use, we used transvaginal prolapse repair studies that compared graft use with either native tissue repair or repair with a different graft. To estimate rates of adverse events from graft use, all comparative studies and case series with at least 30 participants were included. For spectrum of adverse events, all study designs were included.

TABULATION, INTEGRATION AND RESULTS: Eligible studies were extracted onto standardized forms by one reviewer and confirmed by a second reviewer. Comparative studies were classified by vaginal compartment (anterior, posterior, apical, or multiple), graft type (biologic, synthetic-absorbable, synthetic nonabsorbable) and outcome (anatomic, symptomatic). We found 16 comparative studies, including six randomized trials, 37 noncomparative studies with at least 30 women, 11 case series with fewer than 30 women, and 10 case reports of adverse events. One randomized trial and one prospective comparative study evaluating synthetic, nonabsorbable graft use in the anterior compartment reported favorable anatomic and symptomatic outcomes with graft use. Data regarding graft use for posterior and apical compartments or for biologic or synthetic absorbable graft use in the anterior compartment were insufficient to determine efficacy. Rates and spectrum of adverse events associated with graft use included bleeding (0–3%), visceral injury (1–4%), urinary infection (0–19%), graft erosion (0–30%), and fistula (1%). There were insufficient data regarding dyspareunia, sexual, voiding, or defecatory dysfunction.

CONCLUSION: Overall, the existing evidence is limited to guide decisions regarding whether to use graft materials in transvaginal prolapse surgery. Adequately powered randomized trials evaluating anatomic and symptomatic efficacy as well as adverse events are needed.
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** For members of the Society of Gynecologic Surgeons Systematic Review Group who worked on this article, see Appendix 1 online at www.greenjournal.org/cgi/content/full/112/5/1131/DCI.*

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Pelvic organ prolapse (POP), of the anterior vaginal wall, posterior vaginal wall, or vaginal apex are common disorders with substantial psychological, social, and financial impact.[1,2] A woman's lifetime risk for undergoing a surgical intervention for symptomatic pelvic floor disorders is approximately 11%, and approximately 29% of surgically managed patients require reoperation.[3] Abdominal sacro-colpopexy has been shown to provide better apical support success compared with sacrospinous ligament fixation[4]; however, transvaginal repair is commonly performed for prolapse of the anterior, posterior and apical compartments. In an effort to improve outcomes in transvaginal prolapse repairs, multiple biologic and synthetic graft materials have been introduced to complement, reinforce or replace native tissue in reconstructive surgical procedures. The scientific literature about graft use is increasing, but, in general, there are few randomized controlled trials (RCTs) comparing the efficacy of transvaginal prolapse repair with or without graft material. Information regarding both efficacy and adverse events associated with graft use is critical to inform surgeons and patients' choices about whether to use grafts in these repairs. Therefore, we performed a systematic review to evaluate these issues.

The Society of Gynecologic Surgeons' (SGS) Systematic Review Group was formed to provide up-to-date systematic reviews and practice guidelines on pertinent topics in the field of gynecology. The overall aim of this review is to identify, appraise, and synthesize relevant studies regarding graft use in transvaginal POP repair of the posterior, anterior, and apical compartments. Our specific objectives were to 1) estimate the anatomic efficacy of graft use compared with native tissue in transvaginal POP repair, 2) estimate the symptomatic efficacy of graft use compared with native tissue in transvaginal POP repair, 3) compare the anatomic and symptomatic efficacy of different graft materials in transvaginal POP repair, 4) report adverse event rates associated with graft use in transvaginal POP repair, and 5) describe the spectrum of adverse events associated with graft use in transvaginal POP repair.

SOURCES

This review was conducted in conjunction with experts in systematic review methods from Tufts Medical Center following the approach outlined by Counsell.[5] Eligible studies were retrieved through a Medline search for the period between 1950 and November 27, 2007. The search terms included "vaginal or uterine prolapse," "rectocele," "cystocele," "surgery of the pelvic floor," "surgical mesh," "vagina," "rectum," and "bladder" (search details available on request). The search was limited to human studies. We used no language restriction for screening. Studies published in English, French, Hebrew, and German could be reviewed in full text by our group. Review articles were excluded. In addition, reference lists of included studies and selected review articles were reviewed for additional studies.

STUDY SELECTION

For objectives 1 and 2 (comparing anatomic and symptomatic efficacy of repair with graft compared with native tissue only), studies that compared transvaginal POP repair using native tissue with repair using graft were included (RCTs, prospective and retrospective cohorts). For objective 3, (comparing efficacy of different grafts), studies that compared one type of graft with another were included. For objective 4 (rates of adverse events associated with graft use), case series reporting on adverse events with at least 30 patients were added to all comparative studies. For objective 5 (spectrum of types of adverse events from graft use) any study describing an adverse event after use of transvaginally placed grafts was eligible.

We included studies that reported anatomic, symptomatic or adverse event outcomes on any type of graft material in transvaginal POP repairs (excluding abdominal or laparoscopic graft use). To compare anatomic and symptomatic efficacy, we excluded comparative studies that did not use either the Baden-Walker[6] or pelvic organ prolapse quantification (POP-Q)[7] classification methods to decrease heterogeneity and potentially allow for meta-analyses of anatomic outcomes. However, for describing the rates and types of adverse events, we included studies if they reported adverse event data, even if they did not report anatomic outcomes using these classification systems. For studies reporting outcomes at multiple time points, the outcomes with the longest follow-up were used. We did not exclude study populations that received both POP graft repair and a mesh sling.

Potentially relevant studies based on abstract screening were retrieved and evaluated for eligibility. Data in articles meeting eligibility were extracted using a standardized data extraction form developed and tested by our review group. Data extracted included 1) study characteristics (year, design, number enrolled/analyzed, length of follow-up), 2) patient (clinical) characteristics, 3) intervention (type of graft, repair and comparator), and 4) outcomes (anatomic by Baden-Walker or POP-Q; symptomatic including

prolapse, urinary, defecatory, sexual and quality of life; adverse events including visceral injury, bleeding, infection, erosion, and functional adverse events). For each study, data were extracted by one reviewer and a second reviewer confirmed the accuracy of extracted data. Discrepancies were resolved by discussion or by referral to a third reviewer. When necessary, attempts were made to contact authors for additional information.

We assessed the methodological quality of each study based on predefined criteria using a three-category grading system (A, B, C) modified from the Agency for Healthcare Research and Quality grading system, which has been used in previous evidence reports from the Tufts Evidence Practice Center as well as in evidence-based clinical practice guidelines.[8] This system defines a generic grading system that is applicable to various study designs including RCTs and nonrandomized comparative trials, cohort, and case-control studies. Studies are designated as good, fair or poor quality based on the likelihood of biases and the completeness of reporting. The quality grade can vary for different outcomes in the same study. The details of our quality assessment grading are further described in a companion article. [9]

We decided a priori that meta-analyses would only be performed for studies with similar interventions, study designs and outcome definitions and that at least three similar studies would be needed to perform meta-analysis. For anatomic efficacy, we decided that studies must also include baseline measures, 1-year minimum follow-up, recurrence classified using Baden-Walker or POP-Q, and clear definitions of recurrence. For symptomatic efficacy, studies must include baseline symptom assessment in addition to postoperative assessment. Unfortunately, no sets of studies met these criteria, so meta-analysis was not performed.

Clinical practice guidelines and recommendations were developed by our group based on findings from this systematic review. The methods and guidelines are detailed in a companion article.[9] As part of a public vetting process, the methods and findings of this systematic review and our draft clinical practice guidelines and recommendations were presented and available for comment at the 34th SGS Annual Scientific Meeting on April 14, 2008. The guidelines and recommendations were then posted on the official SGS website and public comments were solicited for an additional 4 weeks. Additionally, we solicited comments from five experts in the field of reconstructive pelvic surgery who were not members of the Systematic Review Group and addressed their comments in revised drafts of the systematic review and guidelines.

RESULTS

The Medline search identified 2,260 citations. After abstract screening, 196 full text articles were assessed in detail. For studies reporting on the same cohort of women, we included the study with the most complete efficacy data and/or the longest follow-up time and excluded the remaining.[10–19] A total of 74 articles met all inclusion criteria. These included 16 comparative studies which evaluated efficacy of graft use,[20–35] six of which were RCTs. The remaining 58 studies that met eligibility for adverse event outcomes included three comparative studies,[35–37] 37 noncomparative studies with at least 30 participants,[38–74] 11 noncomparative studies with fewer than 30 participants,[75–85] and 10 case reports.[86–95]

The 16 comparative studies were used for objectives 1–3 (comparing anatomic and symptomatic efficacy of graft compared with no graft or different types of grafts). Women from these studies underwent surgery between the years 1989 and 2005. In general, the quality of studies was variable, which influenced our ability to formulate conclusions or to perform meta-analyses. Most studies were inadequately powered or did not report sample size justifications. The reported sample sizes were highly variable, ranging from n=12 to n=214 per arm. Although some studies reported the proportion of primary compared with recurrent repairs and all studies reported that concurrent repairs were performed, outcomes were not consistently reported for these subgroups. Outcomes and study details for comparative studies are provided in Table 1. Additional study details and adverse events are provided in Tables 2–4 in the Appendix (see Appendix 2 online at www.greenjournal.org/cgi/content/full/112/5/1131/DC2).

Three studies examined the results of posterior vaginal wall surgery using biologic graft compared with native tissue.[20–22] In the only published RCT, Paraiso et al reported on 106 patients with stage 2 or greater posterior vaginal prolapse, randomized to posterior colporrhaphy (n=37), site-specific repair only (n=37), or site-specific repair augmented by acellular porcine small intestinal submucosa graft (Fortagen, Organogenesis, Inc, Canton, MA; n=32).[20] Braided polyester suture was used in all three arms for plication. The graft was secured with delayed absorbable polydiaxanone suture. After 1 year (mean follow-up of 17.5±7 months), patients who received a Fortagen-augmented site-specific repair exhibited failure (Bp-2 or greater on POP-Q) at a greater rate

Table 1. Description of Comparative Studies on Graft Use in Transvaginal Pelvic Organ Prolapse Repair

Study Author, y	Study Design (Quality)	Graft Type (n)	Comparator (n)	Mean Length of Follow-up, mo (Range)	Percent Followed Up	Anatomic Failure, Definition (Rate per Intervention, %)	Symptomatic Outcomes	Sexual Function Outcomes
Posterior Compartment								
Paraiso,[20] 2006	RCT (A)	Fortagen (31)	Traditional (37) Site-specific (37)	17.5 (4.4–33.7)	Fortagen 84 Traditional 76 Site-specific 73	Bp −2 or greater on POP-Q Fortagen (46) Traditional (14) Site-specific (22), *P*=.02	PFDI, PFIQ, NS	PISQ-12, NS
Altman,[21] 2004	Prospective, historical controls (C)	Pelvicol (17)	Traditional (15)	12 (9.3–12.9)	Pelvicol 100 Traditional N/A	POP-Q Stage 2 or greater Pelvicol (12) Traditional (13), *P* NR		
Novi,[22] 2007	Prospective cohort (C)	Pelvicol (70)	Site-specific (40)	6	Pelvicol 100 Site-specific 100			PISQ-12, no difference between groups
Sand,[23] 2001	RCT (B)	Vicryl mesh (73)	Traditional (70)	12	Vicryl 89 Traditional 96	Grade 2 or greater modified BW Vicryl (9) Traditional (10), NS		
Anterior Compartment								
Meschia,[25] 2007	RCT (B)	Pelvicol (100)	Traditional (106)	12	Pelvicol 98 Traditional 97	Ba −1 or greater on POP-Q Pelvicol (7) Traditional (19), *P*=.02	Prolapse sensation, NS	Dyspareunia, NS
Gandhi,[24] 2005	RCT (B)	Tutoplast (76)	Wide plication (78)	Median 13	Tutoplast 100 Wide plication 100	Grade 2 or greater/stage 2 on BW or POP-Q Tutoplast (21) Wide plication (30), NS	Bulge NS, pelvic pain *P*=.07	
Handel,[27] 2007	Comparative w/historical controls (C)	Pelvicol (56), Polypropylene (25)	Traditional (18)	13.5 (2–46)	N/A	Grade 2 or greater on BW Pelvicol (36) Polypropylene (4) Traditional (6) *P* NR		
Chaliha,[26] 2006	Retrospective cohort (C)	SIS (14)	Traditional (14)	24	N/A	Mean Ba on POP-Q at 24 mo, NS	Prolapse impact mean score on P-QOL, NS	
Sand,[23] 2001	RCT (B)	Vicryl mesh (73)	Traditional (70)	12	Vicryl 100 Traditional 100	Grade 2 or greater modified BW Vicryl (25) Traditional (43), *P*=.02		
Weber,[28] 2001	RCT (B)	Vicryl mesh (35)	Ultralateral plication (39) Traditional (35)	Median 23.3	Vicryl 74 Ultralateral 62 Traditional 94	Stage 2 or greater on POP-Q Vicryl (58) Ultralateral (54)Traditional (70), NS	POP severity on visual analogue scale, NS	Sexual symptoms on visual analogue scale, NS
Hiltunen,[29] 2007	RCT (A−)	Polypropylene (105)	Traditional (97)	12	Polypropylene 99 Traditional 99	Stage 2 or greater on POP-Q Polypropylene (7) Traditional (39), *P*<.001	Vaginal bulging, NS	
Julian,[30] 1996	Prospective cohort (C)	Marlex (12)	Traditional (12)	24	Marlex 100 Traditional 100	Greater than grade 0 on modified BW Marlex (0) Traditional (33), *P*<.05		
Bai,[31] 2007	Prospective cohort (C)	Polypropylene (28)	Traditional (72), internal (38)	12	Polypropylene 100 Traditional 100 Internal 100	Outcome undefined Polypropylene (0) Traditional (1) Internal (18), *P*=.001		
Leboeuf,[32] 2004	Prospective cohort (C)	Pelvicol (19)	Vicryl (24)	15 (6–48)	Pelvicol 100 Vicryl 100	Grade 2 or greater on BW Pelvicol (16) Vicryl (0), *P* NR	Mean SEAPI score, *P* NR	
Deffieux,[33] 2007	Retrospective cohort (B)	Gynemesh (89)	Gynemesh-soft (49)	6	N/A	Greater than stage 2 on POP-Q Gynemesh (3) Gynemesh-soft (8), *P* NR		

(*continued*)

Table 1. Description of Comparative Studies on Graft Use in Transvaginal Pelvic Organ Prolapse Repair (*continued*)

Study Author, y	Study Design (Quality)	Graft Type (n)	Comparator (n)	Mean Length of Follow-up, mo (Range)	Percent Followed Up	Anatomic Failure, Definition (Rate per Intervention, %)	Symptomatic Outcomes	Sexual Function Outcomes
Multiple Compartments, Multiple Graft Types								
Vakili,[34] 2005	Retrospective cohort (C)	Multiple biologic and synthetic grafts (98)	No graft (214)	Median 9	N/A	Greater than grade 0 on BW Graft (35) No graft (43), NS		

RCT, randomized controlled trial; POP-Q, pelvic organ prolapse quantification; PFDI, Pelvic Floor Distress Inventory; PFIQ, Pelvic Floor Impact Questionnaire; PISQ, Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire; NS, not significant; N/A, not applicable; *P* NR, *P* value not reported; BW, Baden-Walker; SEAPI, stress, emptying, anatomy, protection and instability test.

(12/26, 46%) than those who received site-specific repair only (6/27, 22%) or traditional posterior colporrhaphy without levatorplasty (4/28, 14%, *P*=.02). The median Bp measurement at 1 year was statistically greater in the graft augmentation group (−2, range −3 to +1) than in the posterior colporrhaphy group (−3, range −3 to 0) or site-specific repair group (−3, range −3 to 0, *P*=.02). Shorter time to recurrence was also seen in those receiving xenograft than in those receiving posterior colporrhaphy alone (*P*=.046).

Although not the primary outcome, Altman et al reported the anatomic outcome of placing cross-linked porcine dermis (Pelvicol, CR Bard, Covington, GA) into the rectovaginal space as a stand-alone posterior vaginal prolapse repair in 17 patients with POP-Q stage 2 or greater posterior vaginal wall prolapse.[21] The graft was secured with polyglactin sutures without plication or site specific repair. Outcomes were compared with 15 age-matched historical controls who had previously received a posterior colporrhaphy without graft. At 6 months, 15 patients receiving Pelvicol exhibited stage 1 prolapse and two had stage 2, whereas 14 patients who had no graft exhibited stage 1 prolapse and one had stage 2 in the posterior compartment.

Symptomatic outcomes were reported by Paraiso et al and were uniform among each of the three aforementioned groups, with statistically significant improvements seen at 1 year in the prolapse, colorectal and urinary scales of the Pelvic Floor Distress Inventory (PFDI-20) and Pelvic Floor Impact Questionnaire (PFIQ-7) in all groups.[20] There were no differences for the POP, colorectal–anal, or urinary distress or impact subscales of the PFDI or PFIQ between groups at 12 months. The percentage of patients reporting dyspareunia "usually or always" was similar in all groups. Finally, no differences were observed in the global index of improvement ("much better" or "better" after surgery) among the groups: posterior colporrhaphy, 74%; site-specific only, 88%; and graft augmented, 90%.

Novi et al assessed sexual function in women 6 months postoperatively, employing the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12) in two separate cohorts: those who received Pelvicol reinforced posterior repair without plication or site specific repair by a urogynecologist (n=50) and those who received site-specific repair with polyglactin suture by a colorectal surgeon (n=50).[22] The Pelvicol graft was affixed with braided polyester suture. No patient underwent levatorplasty. At 6 months, within-group PISQ-12 scores in the Pelvicol group improved (19.9±2.2 point change, *P*=.01), whereas there was no difference in the no graft group (6.9±3.1 point change, *P*=.08). Between groups, the Pelvicol group had improved PISQ-12 scores compared with the no graft group (101.3±6.4 compared with 89.7±7.1, *P*=.01). Dyspareunia improved in both groups.

Only one study evaluated synthetic absorbable graft compared with native tissue in the posterior wall.[23] Sand et al performed an RCT to primarily evaluate mesh use in the anterior compartment, but also evaluated the effect of graft use in the posterior compartment. Women with anterior vaginal prolapse to or beyond the hymen were randomized to traditional anterior and posterior colporrhaphy with polyglactin suture (n=70) compared with anterior and posterior repair augmented with polyglactin 910 mesh (Vicryl mesh, Ethicon, Somerville, NJ; n=73). The number of women ultimately having posterior repair in this study included 67 in the no graft group and 65 in the graft group. Three 2×3 cm pieces of Vicryl mesh were folded into the imbricated endopelvic connective tissue at three sites: underneath the trigone, anterior to the vaginal cuff, and cephalad to the deep transverse perineal muscles. At 1 year, three patients in each group had a recurrent posterior vaginal wall prolapse to the hymen (grade 3 or greater

on modified Baden-Walker) and no patient exhibited recurrence beyond the hymen (grade 4 on modified Baden-Walker, $P=.96$). Symptomatic outcomes were not reported.

No study compared synthetic nonabsorbable graft with native tissue repair in the posterior compartment or compared two different graft types in the posterior compartment.

Four studies compared anatomic outcomes of anterior repair with and without biologic graft.[24–27] In Gandhi's RCT, patients were assigned to "ultralateral" anterior colporrhaphy with polyglactin sutures (n=78) or ultralateral colporrhaphy with solvent dehydrated human fascia lata (Tutoplast, Mentor Corporation, Santa Barbara, CA) secured over the repair (n=76). Gandhi's[24] trial showed a trend for improved anatomic outcomes with graft use, although these results were not statistically significant (recurrence 16/76 Tutoplast compared with 23/78 no graft, $P=.23$; failure stage 2 or greater on POP-Q or grade 2 on Baden-Walker).

Meschia randomized women with stage 2 or greater anterior prolapse undergoing primary repair to anterior repair with polyglactin suture plication (n=103) or Pelvicol reinforcement over plication (n=98). The Pelvicol was secured with polydioxanone suture.[25] In this trial, Pelvicol was associated with a decreased recurrence rate (failure point Ba −1 or greater on POP-Q) at 1 year (7/98 Pelvicol compared with 20/103 no graft group, $P=.019$).

Two retrospective studies assessed anatomic efficacy of biologic graft use compared with native tissue repair in the anterior compartment. Chaliha compared anterior colporrhaphy with 0 Vicryl suture (n=14) to colporrhaphy reinforced with a folded piece of submucosa xenograft (manufacturer not reported) secured over the area with 3–0 PDS (n=14).[26] The authors found no difference between the two groups for mean improvement of point Ba on POP-Q examination at 24 months ($P=.83$). Handel compared two types of grafts and traditional repair in the anterior compartment.[27] The three groups included: 1) plication of the pubocervical connective tissue and the uterosacral-cardinal ligament complex (n=18); 2) porcine-dermis (manufacturer not reported) (n=56); or 3) polypropylene graft (manufacturer not reported) anchored to the levator fascia and uterosacral-cardinal complex (n=25). Surgical approach was determined by the surgeon and no specific inclusion criteria were described. Recurrence (grade 2 or greater on Baden-Walker) at a mean of 13.5 months was not different between groups (20/56 porcine-dermis, 1/25 polypropylene, 1/18 no graft group, P value not reported). Neither study reported sample size justifications.

Across studies, the interventions and outcomes evaluated were sufficiently different from each other that meta-analysis was not appropriate.

Three studies compared symptomatic outcomes of biologic graft use compared with no graft in the anterior wall.[24–26] Short-term subjective symptoms, such as pressure, vaginal bulge, lower urinary tract symptoms, dyspareunia, abdominal and pelvic pain did not differ between patients who underwent surgery with biologic graft and those who had native tissue repairs.

Two RCTs assessed anatomic outcomes of synthetic absorbable graft compared with no graft in the anterior compartment.[23,28] Both evaluated the use of Vicryl mesh. Sand's RCT has already been described. Weber's RCT compared three methods of anterior repair: 1) "traditional" plication without tension using polydiaxonone suture, 2) "ultralateral" plication using polydiaxonone suture and placing the pubocervical connective tissue under tension, and 3) traditional plication reinforced with Vicryl mesh.[28] One hundred fourteen women were randomized; however, the study did not recruit enough women to achieve power to detect differences between groups for the primary outcome of recurrence.

Anterior prolapse recurrence rates differ between the Sand and Weber studies. The overall failure rate (grade 2 or greater on Baden-Walker) in Sand's study was 34% at 12 months compared with Weber's failure rate (stage 2 or greater on POP-Q) of 61% at 23.3 months. Sand found that women randomized to Vicryl mesh had a statistically significant lower failure rate (18/73 Vicryl compared with 30/70 no graft, $P=.02$) whereas Weber found no difference (15/26 for Vicryl mesh, 13/24 ultralateral, 23/33 no graft, P value not significant). These two trials and outcomes were not similar enough to allow pooling of data for meta-analysis.

Only Weber's study evaluated symptomatic outcomes including severity of POP symptoms, urinary symptoms and sexual symptoms measured using visual analog scores.[28] No differences between the three groups were noted, although the study was not powered to find differences in these secondary outcomes.

Three articles compared the anatomic efficacy of synthetic nonabsorbable graft compared with no graft in the anterior compartment.[29–31]

Hiltunen randomized 202 women to anterior colporrhaphy with or without a low weight polypropylene mesh (Parietene light, Sofradim Co., Trevoix, France).[29] In 40% of those randomized to graft, the

graft was fixed using absorbable suture. Patients were excluded if they had stress urinary incontinence symptoms, apical defects or if the main symptomatic prolapse was the posterior vaginal wall. Hiltunen reported lower recurrence (stage 2 or greater POP-Q) at 1 year with mesh (7/104 polypropylene compared with 37/96 no graft, $P<.001$).

Two prospective cohort studies were also identified.[30,31] In Julian's study, 24 women with recurrent grade 3–4 anterior wall prolapse underwent anterior repair with or without polypropylene graft (Marlex Bard Vascular System Division, CR Bard, Billerica, MA).[30] Julian reported lower recurrence (greater than grade 0 Baden-Walker) at 2 years with graft (0/12 Marlex compared with 4/12 no graft, $P<.05$). Bai performed a prospective cohort study comparing three types of anterior repair: anterior colporrhaphy (n=72), anterior colporrhaphy reinforced with polypropylene mesh fixed with polyglactin suture (n=28) and anterior vaginal wall repair via laparotomy (n=38).[31] Cointerventions were not reported. Bai found recurrence (undefined) to be different among all three groups (0/28 transvaginal with polypropylene graft, 1/72 transvaginal with native tissue, 7/38 internal repair via laparotomy, $P=.001$); however, although likely underpowered, there was no difference between the transvaginal graft and native tissue repairs.

Although Hiltunen and Julian's studies were similar enough to consider pooling anatomic outcome data, the small size of Julian's study would not have resulted in a significant effect on the overall findings of Hiltunen's larger study.

Only Hiltunen reported on symptomatic outcomes including pelvic pressure, vaginal bulging, and difficulty with bladder emptying.[29] These outcomes were not statistically significantly different between groups.

Three studies comparing anatomic efficacy of at least two different graft types in the anterior compartment were identified.[27,32,33] The study by Handel has previously been described and showed no difference between porcine dermis, polypropylene and traditional anterior repair, although the study was not powered.[27] Leboeuf performed a prospective comparative study on 43 patients who had anterior repair surgery for grade 4 anterior vaginal prolapse.[32] The first 24 surgeries included the use of a Vicryl mesh and the subsequent 19 were augmented with Pelvicol. The Vicryl mesh surgeries included paravaginal repair, cardinal ligament plication and a needle suspension surgery. The Pelvicol procedure was similar except a tension free mid-urethral sling or Pelvicol sling was used instead of the needle suspension for incontinence. Of the 43 patients, six had at least one prior surgery for anterior vaginal wall prolapse or stress incontinence. No differences in recurrence (grade 2 or greater on Baden-Walker) were found between the two graft groups (3/19 Pelvicol compared with 0/24 Vicryl mesh, *P* value not reported), although the study was not powered.

Deffieux performed a retrospective cohort study comparing Gynemesh (n=89) and Gynemesh-Soft (n=49) permanent polypropylene meshes (Johnson and Johnson, New Brunswick, NJ).[33] All patients had an anterior colporrhaphy with tension-free (no suturing) mesh placement. The 6-month recurrence rate (greater than stage 2 POP-Q) was not statistically different between the two groups (3/89 Gynemesh compared with 4/49 Gynemesh-soft, *P* value not reported), although this study was not powered. These studies were not similar enough in design or quality to allow pooling of data.

Only Leboeuf reported symptomatic outcomes.[32] Subjective outcomes were measured using the stress, emptying, anatomy, protection and instability test. Both graft groups showed improvement in scores from baseline, although there was no difference between the two groups. This study was not powered to find differences in these scores.

There were no eligible comparative studies that compared graft compared with native tissue or different types of grafts for apical support.

One study compared anatomic efficacy of multiple graft types with no graft in different compartments.[34] Vakili et al performed a retrospective cohort study comparing recurrence (greater than grade 0 Baden-Walker) of vaginal reconstructive surgery with and without graft material in any compartment. Graft materials included multiple biologic and synthetic grafts. No differences in recurrence were observed between groups at a median of 9 months (34/98 graft compared with 91/214 no graft, $P=.19$). Symptomatic efficacy was not reported. This study was underpowered, so results should be interpreted with caution.

For objectives 4 and 5 (describing rates and types of adverse events associated with graft use), a total of 74 articles were identified after accounting for articles reporting on the same cohort of women. All adverse event data are presented in Table 3, available in Appendix 2 online at www.greenjournal.org/cgi/content/full/112/5/1131/DC2. Six RCTs,[20,23–25,28,29] 12 prospective and retrospective cohorts,[21,22,26,27,30–37] and 37 noncomparative studies with 30 or more patients were used to estimate adverse event rates.[38–74] In addition, to better appreciate the spectrum of types of adverse events, an

additional 11 case series with fewer than 30 patients[75–85] and 10 case reports[86–95] were included. Adverse events are categorized by type of event, graft type and compartment.

Visceral injuries including bladder, rectal, vaginal perforations and lacerations were reported with the use of both synthetic and non synthetic graft materials and at all sites of prolapse repair. Among comparative studies, the rate of lower urinary tract injury was 1% in Hiltunen's RCT of anterior repair augmentation with synthetic polypropylene mesh[29] and 3.2% after posterior repair with Fortagen in Paraiso's RCT.[20] For trocar-placed grafts, rectal injury ranged from 0–4%[35] and bladder injury was reported to be 0.9%–2.1%.[40,57]

Bleeding complications (including transfusion, hemorrhage and hematoma) were reported in three RCTs, ranging from 0% to 3% for synthetic and biologic graft.[20,25,28] and as high as 15% in Altman's comparative study of Pelvicol.[21] In one non-RCT, bleeding complications were reported to be up to 5.9% for trocar-placed grafts.[35]

The most common infections reported for any graft or site of repair were urinary tract infections and vaginal wound infections. Urinary infections after synthetic graft placement were 8% in Hiltunen's RCT[29] and up to 26%[72] in one retrospective cohort. Rates of urinary tract infection complicating biologic graft use ranged from 0–19% in Paraiso's and Ghandi's RCTs.[20,24]

Operative site infections were more common after use of biologic than synthetic graft materials. With biologic grafts, wound infection rates ranged from 0% in Ghandi's RCT[24] and up to 18.4% in Vakili's retrospective study which included multiple graft types, with the majority being biologic.[34] The reported rate for synthetic graft infection was 1% in one RCT.[29] Based on two noncomparative studies, the rates of operative site infection for trocar-placed grafts reported were 1% and 4%.[50,52] Two small case series reported pelvic abscess in 3% of women after use of polypropylene mesh.[45,69]

Late operative site complications include graft erosion and fistula formation. Two RCTs reported erosions after repairs with synthetic material; graft erosion occurred in 3.8% after anterior repair augmentation with polyglactin 910 mesh,[28] and 17.3% after anterior repair with polypropylene mesh.[29] Graft erosion rates up to 20% were reported in a retrospective cohort of women who underwent anterior repair augmented with polypropylene mesh.[33] The highest rate of erosion was reported in an ambispective study of posterior repair augmented with a composite synthetic mesh (polyglactin 910/popylropylene [Vypro II, Ethicon Products Worldwide, Cincinnati, OH]).[73] In this study, 8% of women were diagnosed with erosion at 6–12 weeks. This rate increased to 29% among patients available for 36 months of follow-up. Vaginal erosion rates after repair augmented with biologic graft were reported by fewer studies, with rates ranging from 0–14% and up to 26% in one large retrospective cohort including all types of graft material with majority being biologic grafts.[34] Mesh erosion after trocar-placed grafts ranged from 1.3–16.9% in noncomparative studies.[44,50]

Erosion of graft material into a viscus with subsequent fistula formation was a rare event reported in six cohort studies[32,39,55,57,60,75]; five of these involved a repair augmented with nonabsorbable synthetic graft. The reported rate of viscous erosion or fistula formation with grafts of any type was 1% in large cohorts.[60] One case series reported a 5.3% rate of fistula formation after trocar-placed grafts.[75]

Other long-term wound complications including granulation tissue formation and granulomas were reported in six studies.[21,34,42,53,66,67] Rates ranged from 3–39% and were more commonly reported after use of biologic graft materials. Based on two noncomparative retrospective studies, the rate of long-term wound complications was 0.9–8.3% after trocar-placed grafts.[61,64]

Functional adverse events collected include sexual, voiding, and defecatory dysfunction. Reports of sexual function after transvaginal repair with graft materials were largely limited to reports of dyspareunia. Furthermore, many studies did not report whether these rates were de novo or worsening of already existing dyspareunia. Dyspareunia rates ranged from 0–17% after repairs with nonabsorbable synthetic mesh, with the highest rate reported to be 61% after posterior repair with synthetic nonabsorbable polypropylene mesh.[45] Fewer studies reported on dyspareunia after use of biologic graft, with rates ranging from 1–10% in noncomparative studies.[42,67] After trocar-placed grafts, dyspareunia and sexual dysfunction rates ranged from 3.1–13%.[60,61]

Voiding dysfunction after prolapse repair ranged from 1–28% after biologic grafts,[42,71] 0–12% for synthetic, nonabsorbable grafts,[36] and 7–12% for trocar-placed grafts.[65] Overactive bladder symptoms and urinary urge incontinence rates were up to 18%[36] and 28%[71] with synthetic and biologic grafts respectively. Defecatory dysfunction rates ranged from 1–10% in two noncomparative studies using nonabsorbable synthetic mesh.[60,73]

Rare adverse events, with rates between 1–3%, include prolonged pain at the operative site, hip pain, or

pudendal neuralgia (data available on request).[50,65–68] Medical adverse events occurred at rates in concordance with traditional repair (1–7%), and included stroke, myocardial infarction, pulmonary complications, and death (data available on request).[20,28,62]

CONCLUSION

The scientific literature regarding graft use in the transvaginal repair of POP includes a variety of study designs from case reports to RCTs. The variety of graft types and their effects in different compartments further contribute to challenges in synthesizing the current literature on this topic. We systematically reviewed the literature and present our data regarding comparative efficacy and adverse events from graft use organized by compartment and graft type.

Overall, there were few comparative studies evaluating graft use in transvaginal POP repair. Most comparative studies were underpowered to detect differences for clinical outcomes, or did not describe power calculations and sample size estimates for primary and/or secondary outcomes, making it difficult to draw meaningful conclusions from studies that failed to show statistically significant differences. Although limited data exist for anatomic outcomes, the data on symptomatic efficacy were very sparse. In addition, it remains unclear whether there are certain subgroups of women who might be more likely to benefit from graft use or who may be at higher risk for developing adverse events. Meta-analysis may be useful to combine underpowered studies to answer these important questions in the future, but at this time, studies are so heterogeneous in terms of completeness of data reporting, population, intervention, and outcome definitions that combining these disparate studies in a meta-analysis would not be meaningful or appropriate.

Among comparative studies evaluating anatomic and symptomatic outcomes, exact definition of failure varied. For example, some studies using the POP-Q defined failure as stage 2 or more, whereas others used various cutoff measures for either points Ba or Bp or mean measurements. In general, pelvic floor symptoms, sexual, bladder and bowel dysfunction were poorly reported as were quality of life outcomes. Validated questionnaires were rarely utilized. Follow-up duration was highly variable, ranging from 4 months to 33.7 months. Not all studies reported the number of patients undergoing repeat surgery in the same compartment or reported data in a way that outcomes for subgroups could not be determined. Finally, lack of standardized surgical techniques further complicates interpretation of this literature.

The use of biologic grafts in posterior vaginal wall repair was not superior to native tissue repair for anatomic or symptomatic outcomes. The use of synthetic absorbable grafts in the posterior compartment does not improve anatomic outcomes over posterior colporrhaphy alone, based on current evidence.

It is unclear whether the use of biologic or synthetic absorbable graft material compared with native tissue repair is beneficial for the anterior compartment. The current evidence may suggest that the use of synthetic, nonabsorbable mesh in the anterior compartment improves anatomic outcomes, but there were not enough data to comment on symptomatic outcomes or adverse events.

No studies compared graft use for apical support.

The quality and design of studies reviewed for adverse event data were variable, weakening the conclusions that can be drawn. For example, many studies did not comment on any adverse events, but we cannot assume that none occurred. In addition to differences in reporting, the types and rates of adverse events varied widely.

Overall, visceral injuries were rare, affecting one patient in every cohort reporting any injury. Routine cystoscopy and rectal examinations are warranted for the immediate recognition and repair of such injuries in the operating room. Bleeding, infection rates and overactive bladder symptoms appear comparable between graft and native tissue repairs.

A clinically important adverse event related to graft use is graft erosion. The majority of erosions were vaginal and rarely affected the urethra, urinary bladder, or rectum.

The effect of graft augmentation on sexual function was limited to reports of dyspareunia; however, absence or presence of sexual pain does not completely characterize sexual function. Limited use of validated measures in most studies, as well as inconsistency in collecting data makes interpretation of these data difficult.

As with all systematic reviews, our results are limited by studies available in the literature. There were not enough data to determine efficacy or adverse events among subgroups of graft materials. We were also unable to compare efficacy or adverse events among women who had surgery for recurrent or severe prolapse compared with those undergoing primary repair. Finally, because of the scope of this project, we focused in this article on rates and spectrum of adverse events associated with graft use but did not include adverse events associated with traditional repairs. Strengths of our study include its robust methods approach, which was guided by methods

consultants at Tufts Medical Center who have expertise in the conduct of systematic reviews and development of clinical practice guidelines. Our review provides a clear picture regarding the state of the current published evidence regarding graft use in transvaginal prolapse repair. We hope to update this review and our guidelines when new studies provide findings that would alter the content of our conclusions or the certainty of our assessments. The accompanying clinical practice guidelines contain recommendations for both clinical practice and future research based on this systematic review (reference pending).

Data in the current literature are insufficient to allow for a complete assessment of anatomic or symptomatic efficacy of graft use in transvaginal POP repair for any compartment. Specific recommendations regarding clinical practice and future research can be found in our companion article, Clinical Practice Guidelines on Vaginal Graft Use From the Society of Gynecologic Surgeons.[9]

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