

Prospective randomized trial of polyglactin 910 mesh to prevent recurrence of cystoceles and rectoceles

Peter K. Sand, MD, Sumana Koduri, MD, Robert W. Lobel, MD, Harvey A. Winkler, MD,
Janet Tomezsko, MD, Patrick J. Culligan, MD, and Roger Goldberg, MD

Evanston, Illinois

OBJECTIVE: Our aim was to evaluate the efficacy of polyglactin 910 mesh in preventing recurrent cystoceles and rectoceles.

STUDY DESIGN: In a prospective, randomized, controlled trial, patients undergoing vaginal reconstructive surgery with cystoceles to the hymenal ring and beyond were randomly selected to undergo anterior and posterior colporrhaphy with or without polyglactin 910 mesh reinforcement. Results were evaluated preoperatively and at 2, 6, 12, and 52 weeks postoperatively.

RESULTS: A total of 161 women were randomly selected for this study. One woman was excluded at the time of surgery, and 17 women were lost to follow-up. Eighty women received mesh, and 80 did not. Both groups were found to be equivalent with respect to age, parity, concomitant surgery, and menopausal and hormone replacement status. Preoperatively 49 women had a central cystocele to the hymenal ring and 111 women had cystoceles beyond the introitus; 91 women had a rectocele to the mid-vaginal plane, 31 to the hymenal ring, and 22 beyond the introitus. After 1 year, 30 (43%) of 70 subjects without mesh and 18 (25%) of 73 subjects with mesh had recurrent cystoceles beyond the mid-vaginal plane ($P = .02$). Eight women without mesh and 2 women with mesh had recurrent cystoceles to the hymenal ring ($P = .04$). No recurrent cystoceles beyond the hymenal ring occurred in either group. Multivariate logistic regression analysis showed concurrent slings to be associated with significantly fewer recurrent cystoceles (odds ratio, 0.32; $P = .005$), whereas the presence of mesh remained significantly predictive of fewer cystocele recurrences in this analysis. Thirteen recurrent rectoceles were noted 1 year postoperatively, with no differences between groups.

CONCLUSION: Polyglactin 910 mesh was found to be useful in the prevention of recurrent cystoceles. (*Am J Obstet Gynecol* 2001;184:1357-64.)

Key words: Cystocele, rectocele, polyglactin 910 mesh, recurrent prolapse, prospective randomized trial

Genital prolapse is a common problem with an especially high prevalence among parous women. Olsen et al¹ found a cumulative risk of undergoing anti-incontinence and/or genital prolapse surgery by age 80 years of 11.1%. Twenty-nine percent of the operations performed in this sample were for recurrent problems. The age-specific incidence of surgery in their study increased with advancing age from 0.96 per 1000 woman-years at ages 30 to 39 years to 6.62 per 1000 woman-years between ages 70 and 79 years. Jorgensen et al² noted similar results in the inci-

dence of genital prolapse surgery in Denmark. The incidence of genital prolapse surgery was 0.66 per 1000 woman-years in the 30- to 34-year-old group and rose to 6.51 per 1000 woman-years by age 65 to 69 years in their study. It is clear from these data that genital prolapse is a common problem that increases in an aging population.

Genital prolapse may be addressed by operative correction, pessary use, or no treatment. When prolapse is treated surgically, the specific defects in support must be carefully addressed to ensure an optimal outcome. Even when these defects are carefully considered by experienced surgeons, failure rates for operative repair of a cystocele may range from 20% to 30%.³⁻⁷ Morley and DeLancey³ found a 22% recurrence rate of cystoceles after sacrospinous vaginal vault suspension in 100 women. Similarly, Shull et al⁴ reported a 30% incidence of cystoceles after sacrospinous vaginal vault suspension, with half of these noted as early as 6 weeks postoperatively. Only 14% of these women had recurrent cystoceles, whereas the other 16% had de novo cystoceles after sacrospinous vaginal vault suspension. Shull et al⁵ also found a 24% recurrent cystocele rate after vaginal and paravaginal repair

From The Evanston Continence Center, Division of Urogynecology, Evanston Northwestern Healthcare, Northwestern University Medical School.

Presented at the Sixty-eighth Annual Meeting of The Central Association of Obstetricians and Gynecologists, Chicago, Illinois, October 18-21, 2000.

Reprint requests: Peter K. Sand, MD, Associate Professor of Obstetrics and Gynecology, Director, Evanston Continence Center, Director, Division of Urogynecology, Evanston Northwestern Healthcare, Northwestern University Medical School, Suite 730, 1000 Central St, Evanston, IL 60201.

Copyright © 2001 by Mosby, Inc.

0002-9378/2001 \$35.00 + 0 6/6/115118

doi:10.1067/mob.2001.115118

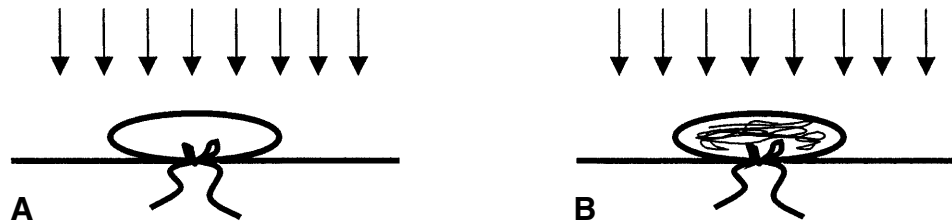


Fig 1. Schematic representation of polyglactin 910 mesh placement. **A**, Standard anterior colporrhaphy. **B**, Anterior colporrhaphy with mesh.

with concurrent vaginal reconstructive surgery in 62 women. In a long-term follow-up study of 243 women who had undergone sacrospinous vaginal vault suspension, Paraiso et al⁶ noted a 37% recurrence of cystoceles and a 14% recurrence of rectoceles. Sze et al⁷ described a 24% recurrence rate for anterior vaginal wall prolapse and found this to be strongly dependent on the concomitant use of a needle-suspension, anti-incontinence operation. They found a 33% recurrence rate when a modified Pereyra procedure was performed with a sacrospinous vaginal vault suspension versus a 14% rate without the modified Pereyra procedure. In a subsequent retrospective analysis of women who had anterior colporrhaphy with or without transvaginal bladder neck suspension, the same group reported a 7% recurrent cystocele rate without and a 33% recurrence rate of cystoceles with concomitant needle suspension ($P < .01$).⁸

From these data it is apparent that the recurrence rate for cystoceles after anterior colporrhaphy and even after transvaginal, paravaginal repair is far too high. In the experience of Shull et al,^{4, 5} as well as in our own experience, even treatment of concomitant paravaginal defects is not always the answer. A well-known answer to high recurrence rates in repair of abdominal hernias has been the use of synthetic mesh. We have used a similar technique for >15 years in vaginal reconstructive surgery at our institution for selected patients with recurrent central cystocele after anterior colporrhaphy. Julian⁹ described his use of Marlex mesh in the repair of recurrent anterior vaginal wall prolapse. In a small, prospective study of 24 women with ≥ 2 recurrences, 12 subjects received Marlex mesh along with anterior colporrhaphy and 12 did not. One third of the control group had recurrent cystoceles, in comparison with none in the group that received Marlex mesh ($P < .05$). Mesh erosion occurred in 3 women (25%) in the first 6 months postoperatively. Our experience with expanded polytetrafluoroethylene mesh has been similar to Julian's, but we have found erosion rates such as he reported to be unacceptable.

An earlier pilot study from our center compared the results of using a synthetic, absorbable mesh (polyglactin 910) during anterior colporrhaphy with the results in previously treated patients who did not receive this ab-

sorbable mesh in their repairs.¹⁰ The mesh was not used as an overlay in our technique but, rather, as a bulking material folded into the anterior colporrhaphy stitches. This approach was thought to enhance scarring just anterior to the suture line, to protect this area, which could potentially be more vulnerable to direct intra-abdominal downward forces (Fig 1). We found a significant decrease in the recurrence of central cystoceles in patients who received the polyglactin 910 mesh, in comparison with recurrence in the previously treated control subjects ($P = .03$).

We then initiated a prospective, randomized, controlled clinical trial to understand whether the addition of polyglactin 910 mesh during primary or recurrent anterior and posterior colporrhaphy improves the outcome of reconstructive surgery in women with a central cystocele protruding to or beyond the hymenal ring.

Material and methods

All women planning to undergo reconstructive pelvic surgery with or without an anti-incontinence operation at The Evanston Continence Center between September 1995 and April 1999, with a cystocele protruding to or beyond the hymenal ring, were invited to participate in a prospective, randomized, controlled trial comparing anterior and posterior colporrhaphy in which polyglactin 910 mesh (Vicryl mesh; Ethicon, Somerville, NJ) was used with colporrhaphy without mesh. This study was approved by the Evanston Northwestern Healthcare Institutional Review Board.

Polyglactin 910 mesh is a tricot knit derived from polyglactin suture yarn, which has the same composition as the suture. It is 90% galactoside and 10% L-lactoside. Polyglactin 910 mesh is 7.5 mil thick and weighs 1.5 ounces per square yard. It has a Mullen burst strength of 60 pounds per square inch and retains at least 25% of its strength beyond 21 days in vivo. The mesh dissolves by hydrolysis and acts as a lattice for the formation of dense granulation tissue. The inflammatory response is minimal. The mesh used in this study was provided by Ethicon, but the company provided no other support for this study and had no input into its design or execution.

Subjects were considered for the trial if they had a cystocele protruding to or beyond the hymenal ring in the standing position while coughing or straining, regardless

of other concurrent prolapse. They had to be >18 years old, ambulatory, and willing to comply with return visits. They were excluded from participating in the trial if they were pregnant or contemplating pregnancy in the next 12 months. They were also excluded if they were found to have only an anterior enterocele or only a paravaginal defect with no need for a central cystocele repair at the time of reconstructive surgery.

A standardized pelvic examination was performed to evaluate the site and degree of pelvic relaxation by means of a modified Baden-Walker scale.¹¹ Cystoceles only in association with paravaginal defects were excluded; all other cystoceles, rectoceles, enteroceles, and uterine and vaginal vault prolapses were graded on a 0- to 4-point scale where 0 was indicative of no prolapse, 1 of prolapse short of the mid-vaginal plane, 2 of prolapse to the mid-vaginal plane, 3 of prolapse to the hymenal ring, and 4 of prolapse beyond the hymenal ring. Demographic data regarding age, parity, prior surgery, and menopausal and hormone replacement status were analyzed. Concomitant surgical procedures besides anterior colporrhaphy were recorded for these subjects.

Subjects were randomly selected on the day of surgery by computer-generated random-number tables either to receive or not to receive polyglactin 910 mesh during anterior colporrhaphy and (if performed) posterior colporrhaphy. Subjects were placed in the dorsal lithotomy position, and a midline incision was made in the anterior vaginal wall from the vaginal apex to the level of the urethrovesical angle. This incision was preceded by vaginal hysterectomy and McCall culdoplasty in women with uterine prolapse, or a transverse incision just distal to the vaginal cuff was made in those who had undergone a prior hysterectomy. Anterior colporrhaphy involved a standard mattress suture repair of the anterior endopelvic connective tissue with the use of size 0 polyglactin sutures. This repair was made after careful dissection of the anterior vaginal epithelium and smooth muscle away from the underlying endopelvic connective tissue laterally to the medial border of the descending pubic rami and posteriorly to the posterior endopelvic connective tissue or rectal reflection if an enterocele was present. If an anterior enterocele was present, it was corrected at this time. Vaginal vault prolapse (if present) was also addressed through the anterior vaginal wall dissection with an anterior sacrospinous vaginal vault suspension. Excess vaginal epithelium was then excised, and the epithelium was closed with size 2-0 polyglactin interrupted figure-of-8 sutures.

Posterior colporrhaphy was similarly performed with a small triangle of epithelium sharply excised from the perineum at the posterior fourchette. A vertical incision was then made in the posterior vaginal wall with Metzenbaum scissors. Mobilization of the endopelvic connective tissue away from the overlying vaginal epithelium and smooth

muscle was performed laterally to the rectal pillars and anteriorly to the uterosacral ligaments. The endopelvic connective tissue was plicated to the midline with interrupted size 0 polyglactin mattress sutures. Similar sutures were placed to plicate the superficial and deep transverse perineal muscles to the midline and to bring the bulbocavernosus muscles to the midline to rebuild the perineum. Excess vaginal epithelium was then resected, and the epithelium was closed with size 2-0 polyglactin sutures in a running fashion. An antibiotic-soaked pack was then placed in the vagina and removed the next morning. A transurethral or suprapubic catheter was placed as indicated by whether the patient had undergone concurrent anti-incontinence surgery. If such surgery was not performed, then the transurethral catheter was removed the next morning.

For patients randomly selected to receive polyglactin 910 mesh, the 6 × 6-inch piece of mesh was divided into 3 pieces. One piece of mesh was folded into the imbricated endopelvic connective tissue underneath the trigone, and a second piece was folded into the imbricated endopelvic connective tissue just anterior to the vaginal cuff. The third piece was used during posterior colporrhaphy, in a similar fashion, just cephalad to the deep transverse perineal muscles. At all 3 sites the mesh was secured within the imbricated fold of endopelvic connective tissue by the first assistant until the surgeon tied the size 0 polyglactin suture encircling the mesh. The addition of the mesh added only seconds to the procedure. Patients were seen at 2, 6, 12, and 52 weeks after surgery, at which time they were reassessed by standard pelvic assessment. Patients were questioned about any adverse effects, and their continence and voiding function were assessed.

The two study groups were compared at baseline, at 12 weeks, and at 1 year for the purpose of this report. Primary outcome variables were recurrent cystocele and rectocele to the mid-vaginal plane or beyond. Recurrent enterocele and apical prolapse were also evaluated in these two study populations.

Statistical evaluation was performed with the Statistical Package for the Social Sciences for Windows (SPSS Inc, Chicago, Ill). Rates of recurrent genital prolapse were compared with the Student *t* test for independent samples. The Mann-Whitney *U* test was used to compare prior operations, concomitant prolapse, and concomitant operations between both groups. Multivariate logistic regression analysis was performed to determine the independent effect of the use of polyglactin 910 mesh on the frequency of recurrent cystocele to or beyond the mid-vaginal plane, with control for potential confounding variables. Covariates entered into the regression model included concomitant needle suspension, retropubic urethropexy, suburethral sling placement, and prior abdominal hysterectomy (because of the significant differ-

Table I. Demographics of 143 women in two study groups with complete follow-up

Demographics	No mesh (n = 70)	Mesh (n = 73)	Statistical significance
Age (y)	62.5	65.0	P = .23
Weight (lb)	147.8	149.9	P = .64
History of smoking	3	2	P = .63
Parity	2.8	2.8	P = .92
Menopausal status (%)	77	82	P = .46
Hormone replacement therapy (%)	46	58	P = .16
Vaginal estrogen replacement therapy (%)	21	22	P = .94

Table II. History of pelvic operation in both study groups with complete follow-up

	No mesh (n = 70)	Mesh (n = 73)	Statistical significance
Total abdominal hysterectomy	13	24	P = .05*
Vaginal hysterectomy	15	12	P = .45
Anterior repair	11	10	P = .74
Posterior repair	10	6	P = .25
Vaginal vault suspension	0	2	P = .16
Retropubic urethropexy	6	6	P = .94
Needle suspension	4	2	P = .38
Suburethral sling	0	3	P = .09

*Statistically significant.

ences found between the study groups for this variable in the univariate analysis).

The sample size was determined by a power analysis that was based on our prior pilot study.¹⁰ Assuming a 2-sided hypothesis test with a 5% type I error and 80% power, we estimated that a sample of 75 patients in each study arm was necessary to detect a 15% reduction in recurrent cystoceles. We assumed a dropout rate of approximately 8% and sought to enroll 162 subjects into the clinical trial.

Results

One hundred sixty-one women were enrolled in the trial; 1 woman was excluded from random selection because she was found to have an anterior enterocele without cystocele intraoperatively. The remaining 160 subjects were randomly selected either to receive or not to receive polyglactin 910 mesh during anterior colporrhaphy and also during posterior colporrhaphy if performed. Eighty subjects were randomly assigned to each group.

Seventeen patients failed to return for the 52-week follow-up. Five of these women had moved to other parts of the country; 2 of them had received mesh during this study. One elderly diabetic patient who had not received mesh died of necrotizing fasciitis from a suprapubic cystotomy incision 6 weeks after operation; her death was

Table III. Concurrent operations performed on patients in both groups with complete follow-up

	No mesh (n = 70)	Mesh (n = 73)	Statistical significance
Vaginal hysterectomy	39	36	P = .45
Paravaginal repair	4	7	P = .39
Posterior repair	67	65	P = .13
Enterocele repair	41	46	P = .59
McCall culdoplasty	27	23	P = .38
Anterior sacrospinous suspension	38	43	P = .58
Posterior sacrospinous suspension	6	5	P = .70
Retropubic urethropexy	18	16	P = .60
Needle suspension	13	10	P = .43
Suburethral sling	21	32	P = .09

thought to be unrelated to the study. Three women refused to return because they were angry about billing issues; 2 of these subjects had received mesh. Two subjects who did not receive mesh refused to return because they were dissatisfied with complications of the anti-incontinence operations. One of these subjects voided by Valsalva maneuver only and had postoperative retention after a sling operation; in the other subject osteomyelitis developed from a bone anchor that was used during the anti-incontinence operation. Two women who did not receive mesh could not return because they were in the end stages of cancer treatment. Three other subjects said that it was too much trouble to return and that they were fine. Two of these women received mesh during operation. One subject who did not receive mesh said that she was having surgery elsewhere and refused to tell us what she was having done and who was doing the surgery.

The remaining 143 subjects completed their 1-year follow-up visits, and their outcome data are the subject of this report. Seventy-three of these women (51%) received polyglactin 910 mesh, and 70 women (49%) did not. Subjects were assessed by standardized pelvic examinations at 12 and 52 weeks postoperatively. There were no adverse events noted from the polyglactin 910 mesh during this trial.

Of the 143 patients, 142 patients were white and one was Asian. The age, weight, smoking status, parity, menopausal status, and hormone replacement status of the 2 groups were similar at baseline (Table I). Table II illustrates no difference in prior reconstructive or anti-incontinence operations between the 2 groups. Abdominal hysterectomy had been performed in more patients in the group receiving polyglactin 910 mesh (n = 24) than in the group not receiving mesh (n = 13; P = .05). All these patients underwent one or, more often, several concomitant reconstructive or anti-incontinence procedures along with anterior colporrhaphy (Table III). There were no significant differences between the two groups in the rates of any of the concomitantly performed operations.

Table IV. Postoperative recurrence data at 12 weeks after surgery for both groups

	No mesh (n = 65)		Mesh (n = 68)		Statistical significance
	No.	%	No.	%	
Cystocele					
Second-degree	7	11.0	5	7.3	<i>P</i> = .50
Third-degree	0		1	1.5	<i>P</i> = .32
Second- or third-degree	7	11.0	6	8.8	<i>P</i> = .71
Rectocele					
Second-degree	1	1.5	1	1.5	<i>P</i> = .98
Third-degree	1	1.5	2	2.9	<i>P</i> = .59
Second- or third-degree	2	3.1	3	4.4	<i>P</i> = .69

There were no significant differences between the two groups on pelvic examination at 12 weeks postoperatively (Table IV). At 1-year follow-up, no differences were found between the two study groups for recurrent enterocele or vaginal vault or uterine prolapse (Table V). Only 5 women had recurrent apical prolapse; in 4 of these the prolapse was only to the midvaginal plane. Two of the recurrent apical prolapses occurred in the group that did not receive mesh, but one of these protruded beyond the introitus and was the only apical recurrence requiring subsequent treatment. Only 3 (2%) of these 143 subjects had an enterocele at 1 year after surgery. Two of these were in the group that received polyglactin 910 mesh. Two women had enteroceles protruding beyond the hymenal ring, 1 in each study group. Of the 143 subjects, 64 had undergone hysterectomy; 27 hysterectomies had been performed vaginally and 37 abdominally (Table II). Seventy-five women had a concurrent vaginal hysterectomy during this study, leaving 4 subjects with an intact uterus. Uterine prolapse beyond the hymenal ring developed in 1 of these women.

At 1 year, 119 (90%) of the 132 subjects did not have recurrent rectocele. Four subjects who did not and 3 who did receive polyglactin 910 mesh had recurrent rectoceles to the midvaginal plane (*P* = .66). Three women in each group had recurrent rectoceles to the hymenal ring (*P* = .96), but none had rectoceles beyond the hymenal ring. In total, 7 women who did not receive mesh and 6 subjects who did receive it had a recurrent rectocele that did not protrude outside the vagina (*P* = .71).

Of the 143 subjects, 95 (66%) had no recurrence of the anterior vaginal wall relaxation or cystocele at 1 year postoperatively. The recurrence of a small cystocele to the midvaginal plane did not differ between the two groups (*P* = .20): 22 women in the no-mesh group and 16 women in the mesh group had recurrent cystocele to the midvaginal plane. However, there was a significant difference in the recurrence rate of cystocele to the hymenal ring between the two groups (*P* = .04). Eight women in the

Table V. Postoperative recurrence data for both groups at 1-year follow-up

	No mesh (n = 70)		Mesh (n = 73)		Statistical significance
	No.	%	No.	%	
Cystocele					
Second-degree	22	31.0	16	22.0	<i>P</i> = .20
Third-degree	8	11.0	2	2.7	<i>P</i> = .04*
Second- or third-degree	30	43.0	18	25.0	<i>P</i> = .02*
Rectocele					
Second-degree	4	5.7	3	4.1	<i>P</i> = .66
Third-degree	3	4.3	3	4.1	<i>P</i> = .96
Second- or third-degree	7	10.0	6	8.2	<i>P</i> = .71

*Statistically significant.

group that did not receive mesh and 2 women in the group that received polyglactin 910 mesh had recurrent cystocele to the hymenal ring. No women had recurrent cystocele beyond the hymenal ring in this study. Overall, 30 (43%) of the 70 women who did not receive mesh had recurrent cystocele. This was significantly greater than the 18 (25%) of 73 women who were randomly selected to receive polyglactin 910 mesh and who had recurrent cystocele of any degree (*P* = .02).

Twenty-one women in this study had been previously treated by anterior colporrhaphy for cystocele. Ten of these subjects were in the group that received polyglactin 910 mesh, and 11 women were in the group that did not (*P* = .74). In the group receiving mesh, 3 women (30%) had recurrent cystocele, as did 4 (36%) of the 11 women in the group that did not receive mesh (*P* = .77). This high-risk group, in whom prior anterior colporrhaphy had failed, were no more likely to have a subsequent recurrence (33%) than the 122 women who had primary cystocele (34%) in this trial (*P* = .98).

Eleven subjects (7.6%) had concurrent paravaginal defects, which were repaired. Seven of these women were randomly selected to receive polyglactin 910 mesh, and 4 women did not receive mesh (*P* = .39). Among the group undergoing paravaginal repairs, only 1 patient who received mesh had a recurrent central cystocele (9%). There were no recurrent paravaginal defects. Concomitant paravaginal repair was significantly associated with a lower recurrence of cystocele overall (*P* = .02) but did not influence the protective effect of mesh placement (*P* = .13). At 1 year after surgery, 5 women (6.8%) who received mesh and 2 women (2.8%) who did not receive mesh had new paravaginal defects that caused recurrent anterior vaginal wall descent (*P* = .27).

Central cystocele recurred in 44 (31%) of the 143 women. Central cystocele recurred in 16 (22%) of the 73 women who received polyglactin 910 mesh and in 28 (40%) of the 70 women who did not receive the mesh

($P = .02$). Only 1 woman in the mesh group and 8 women in the no-mesh group had recurrent central cystocele to the hymenal ring ($P = .01$).

Suburethral sling placement was found to be associated with a significantly lower risk of recurrent cystocele to or beyond the midvaginal plane, according to multivariate logistic regression analysis (odds ratio, 0.32; $P = .005$). Needle suspension ($P = .75$), retropubic urethropexy ($P = .99$), and prior abdominal hysterectomy ($P = .66$) were not significantly predictive of a recurrent cystocele. The independent effect of mesh placement on the risk of recurrent cystocele (central or paravaginal) remained statistically significant after control for suburethral sling placement (odds ratio, 0.48; 95% confidence interval, 0.23-1.00; $P = .05$).

Comment

Numerous surgeons have introduced different techniques to improve the outcome of anterior vaginal wall prolapse—evidence of the difficulty of avoiding recurrent cystocele. Most of these reports are anecdotal. Recently, many surgeons have adapted the hypothesis of Richardson et al¹² that paravaginal defects are responsible for most recurrent cystoceles. Even after using paravaginal repair along with colporrhaphy, Shull et al⁵ and Elkins et al¹³ still noted recurrent cystocele in 24% and 32% of subjects, respectively. This incidence is similar to the 31% incidence of recurrent central cystocele in this clinical trial. These data suggest that the problem of recurrent cystocele is not substantially influenced by the adjunctive use of paravaginal repair.

Many physicians have started using cadaveric fascia lata and dermis to enhance the success of these repairs. These products are 3 to 5 times as expensive as polyglactin 910 mesh and have not been proved beneficial in controlled trials. In the past we used heterologous products for recurrent cystocele with good success; however, as Julian⁹ reported, these products may become infected, and they caused vaginal erosion in 3 (25%) of the 12 women who received Marlex mesh in his trial. There were no vaginal erosions in any of the 80 women randomly selected to receive polyglactin 910 mesh in our trial. This was also true of the 39 subjects in our prior pilot study.¹⁰

This prospective, randomized clinical trial studying the adjunctive use of polyglactin 910 mesh during anterior and posterior colporrhaphy showed that reinforcement of a central cystocele plication with polyglactin mesh significantly reduced the recurrence of cystocele ($P = .02$). There was no effect of this mesh on the success of posterior colporrhaphy; however, the low incidence (9%) of recurrent rectocele after posterior colporrhaphy limits the power of this study to detect a difference between the two study groups.

Sling operation was found to be significantly protective against the development of recurrent cystocele in this

trial ($P = .005$). Unlike Sze et al⁷ and Kohli et al,⁸ we did not find needle-suspension anti-incontinence operations to increase the incidence of recurrent cystocele in this study ($P = .75$) and, in fact, had the opposite effect with a sling procedure. Clearly, because many factors influence the outcome of pelvic reconstructive surgery, further study is required. Developing useful adjuncts to promote the success of these operations is imperative to the improvement of the care of our patients.

This study represents the only prospective, randomized trial of an adjunctive product for use during colporrhaphy that has been shown to decrease the incidence of recurrent cystocele in subjects with primary and recurrent cystoceles. This product was found to be safe, effective, and easy to use. It is important that new products or techniques be carefully tested in controlled trials before they are widely accepted as standard treatments.

REFERENCES

- Olsen AL, Smith VJ, Bergstrom JO, Colling JC, Clark AL. Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence. *Obstet Gynecol* 1997;89:501-6.
- Jorgensen S, Hein HO, Gyntelberg F. Heavy lifting at work and risk of genital prolapse and herniated lumbar disc in assistant nurses. *Occup Med* 1994;44:47-9.
- Morley GW, DeLancey JOL. Sacrospinous ligament fixation for eversion of the vagina. *Am J Obstet Gynecol* 1988;158:872-81.
- Shull BL, Capen CV, Riggs MW, Kuehl TJ. Preoperative and postoperative analysis of site-specific pelvic support defects in 81 women treated with sacrospinous ligament suspension and pelvic reconstruction. *Am J Obstet Gynecol* 1992;166:1764-71.
- Shull BL, Benn SJ, Kuehl TJ. Surgical management of prolapse of the anterior vaginal segment: an analysis of support defects, operative morbidity, and anatomic outcome. *Am J Obstet Gynecol* 1994;171:1429-39.
- Paraiso MFR, Ballard LA, Walters MD, Lee JC, Mitchinson AR. Pelvic support defects and visceral and sexual function in women treated with sacrospinous ligament suspension and pelvic reconstruction. *Am J Obstet Gynecol* 1996;175:1423-31.
- Sze EHM, Miklos JR, Partoll L, Roat TW, Karram MM. Sacrospinous ligament fixation with transvaginal needle suspension for advanced pelvic organ prolapse and stress incontinence. *Obstet Gynecol* 1997;89:94-6.
- Kohli N, Sze EHM, Roat TW, Karram MM. Incidence of recurrent cystocele after anterior colporrhaphy with and without concomitant transvaginal needle suspension. *Am J Obstet Gynecol* 1996;175:1476-82.
- Julian TM. The efficacy of Marlex mesh in the repair of severe, recurrent vaginal prolapse of the anterior midvaginal wall. *Am J Obstet Gynecol* 1996;175:1472-5.
- Lobel RW, Sand PK. The use of polyglactin 910 mesh to prevent recurrence of central cystocele. *Int Urogynecol J*. In press.
- Baden WF, Walker TA, Lindsey JH. The vaginal profile. *Tex Med* 1968;64:56-9.
- Richardson AC, Lyon JB, Williams NL. A new look at pelvic relaxation. *Am J Obstet Gynecol* 1976;126:568-72.
- Elkins TE, Chesson RR, Videla F, Menefee S, Yordan R, Barksdale PA. Transvaginal paravaginal repair: a useful adjunctive procedure in pelvic relaxation surgery. *J Pelvic Surg* 2000;6:11-5.

Discussion

DR BOB L. SHULL, Temple, Texas. Drs Kudori and Sand and associates have posed a question that is clinically important: Will the use of a synthetic, absorbable mesh decrease the failure rates associated with pelvic re-

constructive surgery? Their study design is excellent: they performed a power analysis and designed their study to be prospective and randomized. They knew from their own experience, as well as the experience of other surgeons, that the use of nonabsorbable mesh in the vagina is associated with an unacceptably high rate of complications. This is not surprising when one considers operating in a clean, contaminated field, the vagina. Consequently the authors chose the use of an absorbable mesh whose safety has been previously demonstrated.

What are the characteristics of an ideal mesh? The mesh itself would reinforce a wound early, when intrinsic wound strength is poor, and yet disappear later, when the wound is mature. In the case of fascia, that means >90 days possibly up to 1 year.

How would an ideal mesh be used? In many animal studies the synthetic mesh is placed as an overlay covering the previously approximated fascial edges, with the edge of the mesh sutured to the fascia itself. Dr Koduri and associates employed a different technique by simply placing the mesh in the wound, rather than using it as a reinforcing patch.

Is the use of the patch effective in vaginal reconstructive surgery? The authors concluded that it is effective for reducing the instance of persistent or recurrent cystocele; however, in their 21 patients with previous cystocele repair, patients in whom mesh was used fared no better than those in whom no mesh was used. Regarding the apex and posterior compartment, the use of mesh did not offer the patients any advantage regarding the success or durability of the repair. However, the authors correctly pointed out that the power of the study was not great enough to draw any conclusion about these particular defects.

Who, then, possibly benefits from the use of mesh? Patients with a primary cystocele repair? Possibly!

Unfortunately the experience of Dr Koduri and associates is not much different from that of many of us. The anterior compartment is difficult to manage effectively. Even with the use of mesh, the rate of recurrent cystocele was unacceptably high.

Several factors are related to long-term outcome.

1. We must do a better job of diagnosing specific defects. I believe that most failures in the anterior compartment are in the transverse portion of the pubocervical fascia and are not centrally or paravaginally located. In our most recent series of >300 women in whom we specifically repaired the transverse portion of the pubocervical fascia, along with all other defects, the rate of anterior compartment persistence or recurrence was 7% for prolapse halfway to the hymen and 2% for prolapse to the hymen. We used no mesh.¹

2. What roles do muscle and nerve integrity play in the durability of reconstructive surgery?

3. What is the role of growth factors in promoting healing? It is hoped that recombinant factors that promote wound healing and wound strength will be available to us in the future.

4. Is there an absorbable synthetic mesh that maintains $\geq 90\%$ of its potential strength for >90 days and

causes no problems with erosion, discharge, or dyspareunia? If one exists, I would be interested in using it. The Panacryl suture is reported to have many of these characteristics; however, to the best of my knowledge, it is not presently available as a mesh.

I have the following questions for Dr Koduri:

1. Were the examiners masked for the postoperative examinations?

2. Do you plan to continue the use of the mesh in the posterior compartment reconstruction?

3. Why did you choose to use a synthetic mesh as an insert, rather than an overlay, to reinforce the surgical repairs?

4. What are your current criteria for the use of synthetic absorbable meshes in vaginal reconstructive surgery?

REFERENCE

1. Shull BL, Bachofen CG, Coates KW, Kuehl TJ. A transvaginal approach to repair of apical and other associated sites of pelvic organ prolapse using uterosacral ligaments. *Am J Obstet Gynecol* 2000;183:1365-74.

DR MICHAEL HANDLER, St Louis, Missouri. I am curious about the difference in the complication rate between the mesh patients and the no-mesh patients.

DR VERONICA MALLET, Dearborn, Michigan. I have two questions. First, were the postoperative restrictions uniform in all cases? I also wonder whether the occupations and activities of the patients, both before and after surgery, were taken into consideration when the evaluation was made.

Second, was there a variable absorption rate for the mesh per individual?

DR ROBERT CARPENTER, Houston, Texas. Because I am an obstetrician and not a gynecologic pelvic surgeon, I wish to ask about the exclusion of women who indicated that they intended to become pregnant within 1 year. How many women were planning on future pregnancies? (With ancient training, one usually did this as a definitive surgery after completion of childbearing so that it did not tear down.)

DR SUSAN HENDRIX, Detroit, Michigan. I would like to ask the authors why they chose the Baden-Walker system to compare or to examine their patients, instead of the more standard Pelvic Organ Prolapse Quantitation (POP-Q) system, which has become standard in the pelvic reconstructive surgery field.

In addition, concerning the statistical analysis, were the authors able to control for confounding with the variables? I suspect that a significant effect might not have been found if the regression analysis had included the multiple procedures that were performed.

DR IRVIN KING, Knoxville, Tennessee. What suture was used without the mesh and when the mesh was implanted or attached?

DR KODURI (Closing). I will first answer Dr Shull's questions.

First, the examiners were not blinded, but all the people in the practice were examining these patients postop-

eratively. Because the information was not necessarily in the chart and the examiner postoperatively was not necessarily the surgeon, the necessary information was not always available.

Second, we do plan to continue the use of mesh in the posterior compartment. We are using it particularly for patients with large rectoceles and for those who seem to have poor connective tissue quality. We showed the difference for the cystoceles because the study was powered for this outcome variable. We did not power the study for recurrent rectoceles, but if we had done so, we would probably have seen a difference.

Dr Shull also asked about our current criteria for the use of synthetic absorbable mesh. We are presently conducting a prospective, randomized trial to determine whether cadaveric fascia is effective in preventing recurrent cystocele. If a patient is not enrolled in this study, and, again, if she has a relatively large cystocele or rectocele with poor tissue quality, we are using the polyglactin 910 (Vicryl) mesh.

Finally, Dr Shull noted the high recurrence rates in both our groups. These rates are higher than those reported in the literature, and I believe that the reason is our strict criteria. Because any descent of the vaginal wall was recorded as a cystocele, the numbers were high.

Dr Hendrix asked whether we had any complications that could be associated with the polyglactin 910 mesh. The answer is no. One patient died of necrotizing fasciitis 30 days after her surgery. She had diabetes, and an infection started from her suprapubic catheter incision. We believe that this event was unrelated to our study.

Dr Mallett asked whether the patients had any postoperative restrictions. After all pelvic reconstructive surgery or anti-incontinence surgery, our patients have strict restrictions on activity for 3 months. We allow no lifting of anything weighing >8 pounds (ie, about a gallon of milk) and no bending or straining. Stool softeners are prescribed to prevent straining for the full 3 months, and, of course, pelvic rest is included in the restrictions.

The restrictions for the two groups did not differ: all were under the same restrictions. The occupations were not specifically analyzed, but because a large portion of our population is retired and elderly, I doubt whether there would be a difference in the activity load.

We did not use the POP-Q system because when we started the study in 1995, we were using the modified Baden-Walker system and continued to use it throughout the study. In our current prospective, randomized trial, we are using the POP-Q system.

We did use regression analyses, and both the groups were equal for both. We specifically considered each and every surgery, and therefore we did not believe that regression analysis was needed for looking at the differences. For prior surgeries, total abdominal hysterectomy was significantly different, but analyzing this factor with logistic regression analysis still showed better outcomes with the polyglactin 910 mesh.

We did look specifically at the sling procedure, as well as all the anti-incontinence procedures, and found that slings were highly protective of recurrent cystocele. With controlling for the sling, we still found a significant improvement with the polyglactin 910 mesh between the mesh group and the no-mesh group.

Receive tables of contents by e-mail

To receive the tables of contents by e-mail, sign up through our Web site at <http://www.mosby.com/ajog>. Choose E-mail Notification. Simply type your e-mail address in the box and click the Subscribe button. Alternatively, you may send an e-mail message to majordomo@mosby.com. Leave the subject line blank, and type the following as the body of your message: *Subscribe ajog_toc*.

You will receive an e-mail to confirm that you have been added to the mailing list. Note that table of contents e-mails will be sent out when a new issue is posted to the Web site.