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Rectocele repair: A randomized trial of three surgical techniques including graft augmentation

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KEY WORDS
Rectocele
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Objective: This study was undertaken to compare outcomes of 3 different rectocele repair techniques.
Study design: One hundred six women with stage II or greater posterior vaginal wall prolapse were randomly assigned to either posterior colporrhaphy (n = 37), site-specific rectocele repair (n = 37), or site-specific rectocele repair augmented with a porcine small intestinal submucosa graft (Fortagen, Organogenesis, Inc, Canton, MA; n = 32). Subjects underwent a physical examination and completed 3 validated pelvic floor instruments at baseline and 6 months, 1 year, and 2 years after surgery. Anatomic failure was defined as pelvic organ prolapse quantitation system (POPQ) point Bp ≥ -2 at 1 year.
Results: Of 106 subjects who enrolled, 105 underwent surgery and of those 105, 98 subjects returned (93%) with a mean follow-up of 17.5 $\pm$ 7 months. After 1 year, those subjects who received graft augmentation had a significantly greater anatomic failure rate (12/26; 46%) than those who received site-specific repair alone (6/27; 22%) or posterior colporraphy (4/28; 14%), $P = .02$. There was a significant improvement in prolapse and colorectal scales and overall summary scores of the Pelvic Floor Distress Inventory short form 20 (PFDI-20), the Pelvic Floor Impact Questionnaire short form 7 (PFIQ-7) after surgery in all groups ($P < .001$ for each) with no differences between groups. The proportion of subjects with functional failures was 15% overall, and not significantly different between groups. There was no significant change in the rate of dyspareunia 1 year after surgery and there were no differences between groups. Overall sexual function as measured by the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire short form (PISQ-12) improved significantly in all groups postoperatively ($P < .001$), with no differences between groups.
Conclusion: Posterior colporraphy and site-specific rectocele repair result in similar anatomic and functional outcomes. The addition of a porcine-derived graft does not improve anatomic outcomes. All 3 methods of rectocele repair result in significant improvements in symptoms, quality of life, and sexual function.

Approximately 200,000 women undergo prolapse surgery annually in the United States. An estimated three fourths of women with prolapse have a rectocele.[1] Cundiff and Fenner[2] reviewed and summarized outcomes after posterior colporrhaphy, site-specific repair, transanal repair, and rectocele repair with graft materials.

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Anatomic cure ranged from 76% to 96% for posterior colporrhaphy and from 56% to 100% for site-specific defect repair.

Currently, the use of implants, both synthetic and biologic, in reconstructive pelvic surgery is expanding despite paucity of data. Proposed indications for the use of graft implantation include: suboptimal autologous tissue; need to augment weak or absent endopelvic tissue; unavoidable stress on the repair; need to bridge a space; insufficient vaginal length or caliber; denervated pelvic floor; and surgeon preference. Some investigators have recommended the use of graft material for recurrent prolapse.[3]

The objective of this investigation is to compare anatomic and functional outcomes of 3 different surgical techniques for treating rectoceles: posterior colporraphy, site-specific rectocele repair, and site-specific rectocele repair augmented with a porcine-derived, acellular collagen matrix graft (Fortagen, Organogenesis, Inc, Canton, MA).

Material and methods

This investigation was approved by the Institutional Review Board at the Cleveland Clinic and all patients provided written informed consent for participation. Funding was provided through an unrestricted research grant from Organogenesis, Inc (Canton, MA), who played no role in the design, implementation, analysis, or writing of this manuscript. Patients undergoing surgery for stage II or greater posterior vaginal wall prolapse from June 2002 through December 2004 were invited to participate. Patients were included if they were 21 years or older and did not desire future vaginal delivery. Patients undergoing concurrent prolapse and/or incontinence surgery were also included. Patients were excluded if they underwent concomitant colorectal procedures; if they had an allergy to pork products; or if they were unwilling to accept porcine product implantation.

At baseline, each subject underwent an evaluation that included a standardized history, gynecologic examination using the pelvic organ prolapse quantitation system (POPQ),[4] rectovaginal examination and sacral neurologic examination. All examinations were performed in the supine lithotomy position. If the maximal extent of the prolapse could not be observed in the supine position, patients underwent a standing examination. Medical comorbidities were characterized by using the Charlson Comorbidity Index[5] and functional capacity was estimated using the Duke Activity Status Index.[6] Multichannel urodynamics were performed preoperatively for those patients with symptomatic urinary incontinence or pelvic organ prolapse that extended beyond the hymen. Each subject completed 2 condition-specific quality of life questionnaires (the Pelvic Floor Distress Inventory short form 20 [PFDI-20], the Pelvic Floor Impact Questionnaire short form 7 [PFIQ-7]),[7] and a condition-specific sexual function questionnaire, the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire short form (PISQ-12).[8]

Patients were randomly assigned to 1 of 3 groups (posterior colporrhaphy, site-specific rectocele repair, and site-specific rectocele repair with graft augmentation) by a computer-generated randomization schedule. Group assignments were concealed in consecutively numbered, sealed, opaque envelopes. Postoperatively, it was not possible to blind the surgeons to the treatment allocation. Patients were blinded to treatment allocation in the immediate postoperative period. If they requested, they were informed of their treatment allocation at their 6-week postoperative visit. Institutional review board requirements did not allow us to blind the subjects beyond this point. However, all postoperative assessments and examinations were performed by a nurse who was blinded to treatment assignment.

The patients were administered preoperative antibiotic prophylaxis with 1 g of cefazolin or 100 mg of vibramycin if penicillin-allergic. During the initial dissection for each of the procedures, the vaginal epithelium was opened transversely at the posterior fourchette. The posterior vaginal incision was made in the midline and extended 1 cm above the superior aspect of the posterior vaginal wall defect. Dissection of the vaginal epithelium away from the underlying fibromuscularis extended superiorly to identify the edge of the fibromuscularis, laterally to the medial aspect of the levator ani muscles, and inferiorly to the perineal body.

Posterior colporrhaphy was performed using No. 2-0 braided polyester suture (Ethibond, Ethicon, Inc, Somerville, NJ) in interrupted mattress stitches to plicate the rectovaginal muscularis across the midline similar to the midline rectovaginal fascial plication described by Maher et al.[9] Unlike traditional posterior colporrhaphy, we did not plicate the levator muscles in the midline.

The site-specific posterior repair was performed using the technique described by Cundiff et al.[10] Interrupted stitches of No. 2-0 braided polyester suture (Ethibond, Ethicon, Inc) were placed to reapproximate the broken edges of the fibromuscularis and correct all defects.

The site-specific posterior repair with graft implant was identical to the procedure described above augmented by a 4 × 8 cm Fortagen graft (Organogenesis, Inc). The graft was perforated with a scalpel 1 cm medial from its borders in 3 to 4 rows of 3-mm incision points as recommended by the manufacturer. The graft was secured superiorly to the posterior vaginal fibromuscularis and epithelium with No. 2-0 delayed absorbable polydioxanone suture (PDS, Ethicon, Inc). Laterally, the mesh was attached to the levator ani fascia with interrupted stitches of No. 2-0 braided polyester suture (Ethibond, Ethicon, Inc). In cases in which a