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PelviSoft BioMesh augmentation of rectocele repair: the initial clinical experience in 35 patients

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Abstract Graft materials have been utilized in the repair of posterior vaginal wall defects to enhance anatomical and functional results, and to improve long-term outcomes. We report on our initial series of 35 patients treated with porcine dermal acellular collagen matrix BioMesh (PelviSoft BioMesh, CR Bard, Cranston, R.I., USA), which has alleviated problems with early post-operative vaginal mucosal dehiscence and delayed healing experienced with the use of other graft materials in the posterior vaginal wall.

Keywords PelviSoft BioMesh · Posterior vaginal wall defects · Vaginal mucosal dehiscence

Introduction

Traditional rectocele repair has been primarily accomplished with a midline plication of rectovaginal fascia and/or levator muscles through a transvaginal approach. This approach assumes a generalized weakness or attenuation of the connective tissue of the rectovaginal septum. A major limitation of this approach is that it aims to correct abnormal anatomy by surgical compensation rather than restoration of the rectovaginal septum. This can lead to problems with incomplete bowel evacuation, constipation, and dyspareunia [1, 2, 3]. Weber et al. found that dyspareunia increased from 6 to 26% in 53 women who underwent posterior colporrhaphy with other vaginal reconstructive procedures [4]. Furthermore, while reported success rates with plication techniques have been in the range of 65–75% with

follow-up of 1–2 years, long-term success declines beyond 3 years [1]. After thorough and intensive investigation of pelvic floor anatomy, Richardson demonstrated that rectoceles are due primarily to site-specific tears in the rectovaginal fascia rather than generalized attenuation in the rectovaginal fascia [5, 6]. In the past few years, site-specific defect repair of the rectovaginal septum has gained popularity and reported success with 1-year follow-up ranges from 72 to 85% [7, 8]. The aim of this approach is actual restoration of normal posterior compartment anatomy. Vassallo and Karram highlight the importance of this concept in a recent article on the surgical management of iatrogenic vaginal constriction, which can develop after posterior plication procedures. This problem is probably under-reported and more common than available literature suggests. They have therefore incorporated site-specific defect repair into their surgical practice [9]. Most recently, Kohli and Miklos build the case for graft augmentation of site-specific defect repairs by noting potential limitations of the site-specific repair when used alone. They reported their technique on an initial series of dermal graft augmented rectocele repairs with a success rate of 93% at an average of 1-year follow-up [10]. They point out that in some cases site-specific defects may not be readily identifiable and correctable by the gynecologic surgeon. Also, it may not always be correct to assume that the rectovaginal septum is otherwise unweakened and is of adequate strength after correction of the site-specific defect.

Recent advances in pelvic reconstructive surgery are due in part to the availability of new graft materials that allow reinforcement and repair of large pelvic fascial defects in a manner that achieves anatomical and functional results that may be superior to traditional colporrhaphy procedures. Efforts are ongoing to find materials that achieve superior results while minimizing adverse graft-related effects.

We have used porcine acellular collagen matrix (Pelvicol, C. R. Bard, Cranston, R.I., USA) for the past 2 years for graft-augmented repair of posterior vaginal

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wall defects and have experienced excellent results. However, some of our patients experienced delayed healing and subsequent separation of the vaginal mucosal incision with exposure of the graft, which led to a prolonged healing phase for some individuals. A total of 41 patients underwent this procedure using Pelvicol with 6 patients (15%) experiencing wound separation and delayed healing. These cases presented between 2 and 4 weeks postoperatively with complaints of vaginal discharge without pain or fever. All 41 patients received prophylactic antibiotics preoperatively, copious irrigation with antimicrobial solution intraoperatively, and vaginal packing for approximately 24 h postoperatively. All wounds eventually healed, requiring an additional 3 weeks to 3 months for completion of the healing process. We were unable to identify the cause of wound separation in the six cases; however, we were concerned that relative devascularization of the vaginal mucosa and a lack of contact with underlying rectovaginal septum tissue may have been a contributing factor. With the use of PelviSoft BioMesh, we hoped to alleviate this problem by allowing immediate contact between vaginal mucosa and underlying host tissues through fenestrations in the graft material.

Materials and methods

The Pelvic Organ Prolapse Quantification Score was used in the preoperative and postoperative evaluation of 35 women presenting with posterior vaginal wall defects. Graft-augmented posterior vaginal wall repair was performed alone or in combination with other procedures. The repairs were begun by incising the skin over the perineal body and undermining the mucosa in the midline of the posterior vaginal floor. The dissection was extended to the vaginal apex and carried out laterally to expose the rectocele, the perirectal fascia, and the medial margins of the levator plates. Site-specific repair of rectovaginal fascial defects was performed at this time. Following the site-specific repair, four to five delayed absorbable sutures (2/0 Vicryl, Ethicon, Somerville, N.J., USA) were placed in the medial aspect of the levator plate laterally on one side, beginning near the vaginal apex and continuing distally toward the perineal body. A 4×7-cm piece of PelviSoft BioMesh was affixed to these sutures and laid in place in the rectovaginal space. Using the same type sutures, the graft was then sutured to the levator plate on the opposite side, in reverse order, beginning at the perineal body and working toward the vaginal apex. Excess graft material was trimmed as needed after the graft was in place. In some cases, grafts were trimmed prior to placement. Additional No. 0 delayed absorbable sutures were used to suture the graft to the perineal body. Also, additional delayed absorbable sutures were used to attach the graft near the vaginal apex and/or uterosacral ligaments when available. Perineorrhaphy was performed if needed at this time and then closure of the vaginal mucosa and

perineal skin was accomplished with a continuous No. 2–0 delayed absorbable suture. It was rarely necessary to trim a significant amount of vaginal mucosa, as excessive removal of mucosa can reduce vaginal caliber. A vaginal pack and urinary catheter were placed for the first 12–24 h. Prophylactic antibiotics and antimicrobial irrigation solution were used to decrease the risk of postoperative infection. Our current procedure is primarily the result of our learned experience over some 50 cases of graft augmentation repairs in the posterior compartment. Our technique is similar to that published in detail by Kohli and Miklos with the primary differences involving graft material, suture used, and order of suture placement. Figs. 1 and 2 demonstrate the unique mesh design of the graft material, and Fig. 3 demonstrates the graft after surgical placement in the posterior compartment.

Results

Median age was 54 with a range from 32 to 81 years and average parity was 2.9 (range: 0–9). Follow-up of 35 patients ranged from 6 months to 18 months with a mean of 12 months and has demonstrated good anatomical results; thus far there have been no difficulties with delayed healing. There were no major intraoperative or postoperative complications (infection, abscess, hematoma, hollow viscous injury, blood loss greater than 500 ml, or transfusion). Specifically, previously seen problems with early postoperative vaginal mucosal dehiscence were not encountered in any of these 35 patients. There have been no complaints related to bowel function, and those patients who were sexually active prior to surgery have not experienced problems with sexual function postoperatively. This information however was gathered retrospectively through review of the patients' medical records by the acting surgeons and based primarily on questions asked at the time of follow-up visits. It should be noted that preoperative questioning of patients regarding their bowel function was performed and patients who were felt to have the possibility of bowel motility problems and colonic inertia were referred for further evaluation and not included in

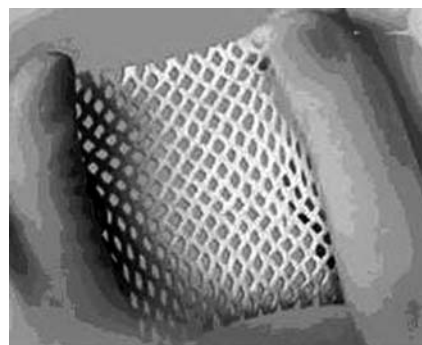


Fig. 1 Unique mesh design of the graft material



Fig. 2 Unique mesh design of the graft material

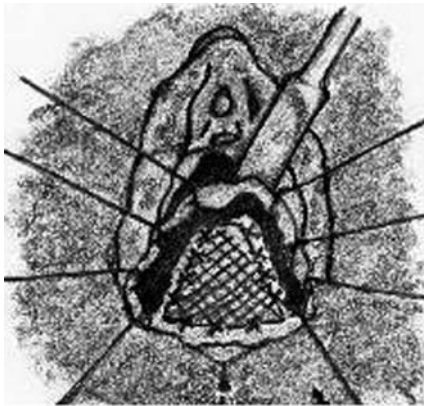


Fig. 3 Graft after surgical placement in the posterior compartment

the series. The average measurement of point Ap was 0.3 preoperatively and -2.3 postoperatively and point Bp was 1.2 preoperatively and -2.5 postoperatively.

Discussion

A variety of both synthetic and nonsynthetic graft materials have been used in the repair of female pelvic floor defects and the search for the “ideal” graft continues. Porcine acellular collagen matrix (Pelvicol, C. R. Bard, Cranston, R.I., USA) has proven in our experience to provide good results when used for graft-augmented repair of posterior vaginal wall defects. Based upon our observations, we believe that the delayed healing and subsequent vaginal mucosal dehiscence seen in some patients may have been related to delayed contact between the vaginal mucosa and underlying tissues caused by the presence of the interposed graft material. We noted that in several patients, there was a noticeable lack of evidence of tissue ingrowth into the graft throughout the extent of the graft for a significant period of time. Our initial experience with PelviSoft BioMesh (C. R. Bard, Cranston, R.I., USA) suggests it may be less susceptible to these problems by allowing immediate contact between vaginal mucosa and underlying host tissues through fenestrations in the mesh graft

material. While we are unaware of published data that would support this theory, our clinical observations of these patients postoperatively are consistent with this hypothesis.

Problems with delayed healing and subsequent vaginal mucosal dehiscence were not reported by Kohli and Miklos in their series of patients using nonfenestrated dermal allograft tissue. Possible explanations for this finding include differences in host response between allografts and xenografts, differences in the harvesting, storing, and cross-linking agents used by tissue companies, and surgical technique used. We are not aware of other published data on the incidence of wound separation following placement of Pelvicol grafts; however, anecdotal evidence obtained through discussions with several other urogynecology centers using Pelvicol suggests that our findings were not unique to our center.

Graft-augmented repair with this new product is in our experience a highly effective technique for management of posterior vaginal wall defects. Further study is needed to document the long-term effectiveness of this product and is currently underway at a number of centers in the United States. The long-term effects of graft augmentation procedures on bowel function and sexual function using this or other materials remain to be seen. Since indications for surgery and definitions of bowel symptoms are not standardized, comparisons of procedures based on the current literature remains challenging at best. While a variety of graft materials, both synthetic and nonsynthetic, are currently available for use in pelvic reconstructive surgery, long-term comparative data are not yet available. Randomized prospective studies with long-term follow-up and documentation of both safety and efficacy using validated questionnaires and quality of life surveys will help clarify the role of graft augmentation repair techniques in the pelvic floor.

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While this alteration of the porcine graft is novel, few conclusions can be drawn from this descriptive case series in regards to any possible benefits it may have over traditional grafts. The lack of standardized follow-up in this series, apart from POP-Q measurements, requires that the reader be skeptical of the stated lack of bowel or sexual complaints following this procedure. Nonetheless, the lack of any serious complications after 1 year of follow-up as reported by the authors is reassuring

Editorial comment

This case series reports the use of fenestrated porcine acellular collagen matrix to augment rectocele repair.