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Original Article

Assessment of Collagen-Coated Anterior Mesh Through Morphology and Clinical Outcomes in Pelvic Reconstructive Surgery for Pelvic Organ Prolapse

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ABSTRACT **Study Objective:** To assess the morphologic features of anterior armed transobturator collagen-coated polypropylene mesh and its clinical outcomes in pelvic reconstructive surgery to treat pelvic organ prolapse.

Design: Evidence obtained from several timed series with intervention (Canadian Task Force classification II-3).

Setting: Chang Gung Memorial Hospital, Taoyuan, Taiwan, China.

Patients: Between April 2010 and October 2012, 70 patients underwent surgery to treat symptomatic pelvic organ prolapse, stage III/IV according to the POP-Q (Pelvic Organ Quantification System).

Intervention: Anterior armed transobturator collagen-coated mesh.

Measurement and Main Results: Morphologic findings and clinical outcome were measured. Morphologic features were assessed via 2-dimensional introital ultrasonography and Doppler studies. Clinical outcome was measured via subjective and objective outcome. Objective outcome was assessed via the 9-point site-specific staging method of the International Continence Society Pelvic Organ Prolapse Quantification before the operation and at 1-year postoperative follow-up. Subjective outcome was based on 4 validated questionnaires: the 6-item UDI-6 (Urogenital Distress Inventory), the 7-item IIQ-7 (Incontinence Impact Questionnaire), the 6-item POPDI-6 (Pelvic Organ Prolapse Distress Inventory 6), and the 12-item PISQ-12 (Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire), at baseline and at 12 months after the operation. Data were obtained for 65 patients who underwent the combined surgery and were able to comply with follow-up for >1 year. Ultrasound studies reveal that mesh length tends to shorten and decrease in thickness over the 1-year follow-up. Vagina thickness also was reduced. Neovascularization through the mesh was observed in <8.5% of patients in the first month and at 1 year, and was evident in approximately 83%. The mesh exposure rate was 6.4%. The recorded objective cure was 90.8% (59 of 65 patients), and subjective cure was 89.2% (58 of 65 patients) at mean (SD) follow-up of 19.40 (10.98) months. At 2 years, UDI-6, IIQ-7, and POPDI-6 scores were all significantly decreased ($p < .001$), whereas the PISQ-12 score was significantly increased ($p = .01$).

Conclusions: Ultrasound features suggest that the degeneration of collagen barrier may be longer than expected and that integration of collagen-coated mesh could occur up to 1 year. A substantially good clinical outcome was noted. Journal of Minimally Invasive Gynecology (2014) ■, ■–■ © 2014 AAGL. All rights reserved.

Keywords: Anterior vaginal mesh; Collagen-coated mesh; Morphology; Outcome; Pelvic organ prolapse

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In the last decade the emergence of commercially available synthetic mesh for use in surgery to treat prolapse has become widespread. This may have been due to the high recurrence rate after prolapse surgery, which has prompted surgeons to seek a more durable method to augment prolapse repair [1]. However, a complication after prolapse surgery using synthetic material is vaginal mesh exposure. With the theoretical protective effect against a strong inflammatory response, host integration, and enhanced tissue repair, some meshes are coated with collagen [2]. In animal studies, vaginal mesh exposure occurred twice as frequently with non-coated polypropylene meshes than with collagen-coated meshes [3]. The Avaulta Plus BioSynthetic Support System (C.R. Bard, Inc., Murray Hill, NJ) is a propylene, collagen-coated, woven vaginal mesh that has a porous, acellular, ultrathin sheet of cross-linked collagen on the central section of the mesh that serves as a protective barrier and contains apertures that enable ingrowth of host tissue and capillary vessels. This product was withdrawn from the US market in 2012 as a commercial decision. However, the manufacture and marketing of Avaulta are cleared by the US Food and Drug Administration and the European Union regulations; thus the product may be sold to other countries including Europe, Taiwan, and China.

The dynamics of pelvic floor ultrasonography have since enhanced our understanding of the effects of new synthetic suburethral slings and surgery to treat prolapse [4] and enabled visualization of modern mesh after surgery. Use of 3- and 4-dimensional ultrasound studies have documented mesh folding [5], and color Doppler enables evaluation of vascular ingrowths within and around the mesh placement area. Hence, ultrasonography may have its benefits for mesh morphologic evaluation during postoperative follow-up.

This objective of the present study was to evaluate the morphologic features and clinical outcomes of collagen-coated polypropylene mesh for the treatment of pelvic organ prolapse. To our knowledge, this is the first study using Doppler ultrasound to evaluate the morphologic features of collagen-coated mesh.

Material and Methods

The present study was performed after obtaining approval from the Chang Gung Memorial Hospital Institutional Review Board. In this case series, 70 patients underwent surgery between April 2010 and October 2012 to treat symptomatic pelvic organ prolapse, stage III/IV according to the POP-Q (Pelvic Organ Quantification System). Patients excluded from the study were those who refused synthetic mesh implantation or who were medically unfit for surgery after cardiopulmonary clearance by a physician. Comorbidities such as diabetes mellitus, hypertension, and constipation were treated and completely corrected before surgery. All patients were counselled about the surgical procedure, informed of the potential benefits and complications of mesh surgery, and gave informed consent. Clinical outcome was measured according to subjective and objective outcomes. Objective outcome was assessed using the 9-point site-specific staging of the International Continence Society POP-Q before the operation and at 1 year follow-up [6]. All patients were asked to complete 4 validated questionnaires: UDI-6 (Urogenital Distress Inventory) [7], IIQ-7 (Incontinence Impact Questionnaire) [8], POPDI-6 (Pelvic Organ Prolapse Distress Inventory 6) [9], and PISQ-12 (Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire) [10,11] at baseline and at 12 months after the operation to measure the subjective outcome.

The choice of anesthesia was according to patient and surgeon preference. The surgical procedures performed, if indicated, would be, in sequence, vaginal total hysterectomy, anterior vaginal mesh placement, sacrospinous ligament fixation, posterior colporrhaphy, and mid-urethral tension-free transobturator sling placement. All surgical procedures were performed by the same surgeon (T.-S.L.), assisted by at least another of us. The surgeon had experience with synthetic meshes in surgery to treat pelvic organ prolapse before the present study [12].

The Avaulta Plus BioSynthetic Support System (C.R. Bard, Inc., Murray Hill, NJ) was used as the mesh deployed at the anterior vaginal wall. Hydrodissection using normal saline solution was performed before full-thickness midline sagittal dissection of the vagina from the bladder. The paravesical space was entered, and the mesh was placed via 4 needle passages, the outside-in transobturator technique, according to the procedural guidelines of the manufacturer. No vaginal trimming was performed. Vaginal sacrospinous ligament fixation using the Miya hook technique as described by Miyazaki [13] was used. A nonabsorbable polypropylene suture was used for fixation. Cystoscopic assessment to confirm the integrity of the lower urinary tract was performed at the end of the procedure. All patients received prophylactic antibiotics (500 mg cefazolin) before surgery and every 6 hours for 1 day after surgery. A Foley indwelling catheter and vaginal pack were left in place for 72 hours. Patients were evaluated for urinary retention before discharge.

Postmenopausal women were offered either systemic or local intravaginal estrogen therapy before and after the surgery unless contraindicated or patient refusal. Patients were followed up at 1 week, 1 month, 3 months, and 6 months, and annually thereafter.

Pelvic examinations were performed by at least one of us. The same surgeon (T.-S.L.) performed 2-dimensional introital ultrasonography with the patient in a semi-supine position. A 3.5-MHz curved linear array transducer (Philips HD11XE; Philips Ltd., Amsterdam, the Netherlands) was positioned adjacent to the vaginal introitus for investigation of the morphologic features of the implanted mesh in the sagittal and transverse planes. Assessment of the pelvic floor was performed using 2-dimensional studies at rest, dynamic evaluation with coughing and the Valsalva maneuver, 4-dimensional reconstruction, and Doppler studies. Important